CROSSVENT-3+
INTENSIVE CARE/TRANSPORT VENTILATOR

OPERATION & SERVICE MANUAL

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CE 0086

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TABLE OF CONTENTS

I. PATIENT SAFETY, WARNINGS, CAUTIONS AND NOTES 1

WARNINGS 1

CAUTIONS 4

NOTES 5

SYMBOLS 7

II- UNPACKING AND ACCESSORIES 8

A- UNPACKING 8

B- ACCESSORIES 8

III. SPECIFICATIONS, CONNECTIONS AND USER INTERFACE 9

A- GENERAL DESCRIPTION 9

B- SPECIFICATIONS 10

C- MANUAL CONTROLS AND CONNECTIONS 11

1- FRONT OF VENTILATOR 11
FLOW CONTROL KNOB 11
MAXIMUM PRESSURE KNOB 11
PEEP KNOB 11
AUDIBLE ALARM 11
ALARM LED 11

2- RIGHT SIDE OF VENTILATOR 12
GAS SUPPLY INLET 12
GAS SUPPLY WITH BLENDER 12
GAS SUPPLY WITH ENTRAINMENT 12
BLEED EXHAUST 12

3- LEFT SIDE OF VENTILATOR 12
POWER ON/OFF SWITCH 12
EXTERNAL ELECTRICAL SUPPLY CONNECTOR 13
CHARGING LED & BATTERY 13
FLOW SENSOR (PNEUMOTACH) 14
OXYGEN SENSOR CONNECTOR 14
EXHALATION VALVE CONNECTOR 14
AIRWAY PRESSURE CONNECTOR 14
PATIENT GAS CONNECTOR 14
ALARM RESET SWITCH 14

4- REAR OF VENTILATOR 15
MAXIMUM PRESSURE RELIEF VALVE 15
NEGATIVE PRESSURE RELIEF VALVE 15
CE MARK 15

D- DISPLAY INTERFACE AND MENUS 16

1- DISPLAY OVERVIEW 16
SELECT AND ADJUST A FUNCTION 16

2- BACKLIGHT& PRESSURE BAR GRAPH 16
AIRWAY PRESSURE BAR GRAPH 16
BACKLIGHT 16

3- MAIN MENU 16
ASSIST CONTROL 17
SIMV 17

CPAP 17
MANUAL 17
PRESSURE TRIGGER 17
PRESSURE SUPPORT 17
RATE 18
SIMV RATE 18
BACKUP RATE 18
TIDAL VOLUME (TV) 18
INSP 18
I, E, I/E KEY 18
FLOW KEY 18
4- ALARM MENUS 19
ALARM MENU KEY 19
ALARM PARAMETER RANGES AND ALARM LIMITS 19
ADDITIONAL ALARMS OUTSIDE OF THE ALARM MENUS 20
ALARM 3 20
NOTES REGARDING ALARMS 21
5- KEYS COMMON TO ALL MENUS 21
LOCK 21
ALARM QUIET 21
ARROW KEYS 22
SIGH 22
POWER SOURCE KEY 22
INSPIRATORY SOURCE KEY 22
SETUP KEY 23

IV. SETUP AND OPERATING INSTRUCTIONS 24

A- INSTALLATION 24
1. MOUNTING OPTIONS 24
2. POWER CONNECTIONS 24

B- PATIENT CIRCUIT CONNECTIONS 25

C- OPERATING INSTRUCTIONS 26
1- PRELIMINARY STEPS 26
2- DETAILED OPERATING INSTRUCTIONS 26
3- SUMMARY OF OPERATING INSTRUCTIONS 27

V. SETUP MENU AND TROUBLESHOOTING 28

A- SETUP MENU 28
1- OXYGEN SENSOR CALIBRATION 28
2- LEAK TEST 28
3- TV/INSP PREFERENCE 28
4- LANGUAGES 28
5- VER (Version) 28
6- SN (Serial Number) 28

B- CALIBRATION MENU (CAL) 29

C- OPERATIONAL TROUBLESHOOTING 30

VII. CLEANING, STERILIZATION AND PACKING 32

A- CLEANING AND STERILIZATION 32

B- PACKING FOR SHIPMENT 33

VIII. THEORY OF OPERATIONS 35

A- SYSTEM COMPONENTS 36

SUPPLY GAS INLET FILTER 36
SUPPLY PRESSURE SENSING SWITCH 36
AIRWAY PRESSURE TRANSDUCER 36
DIFFERENTIAL PRESSURE TRANSDUCER 36
MAXIMUM PRESSURE RELIEF VALVE 36
DIAPHRAGM ACTUATED RELIEF VALVE (D.A.R.V.) 36
NEGATIVE PRESSURE RELIEF VALVE 36

B- ASSIST CONTROL MODE 37

C- SIMV (Synchronized Intermittent Mandatory Ventilation) MODE 38

D- CPAP (Continuous Positive Airway Pressure) 39

E- BACKUP MODALITY 40

IX. MAINTENANCE AND SERVICE 41

A- SETUP & CALIBRATION MENU OVERVIEW 41
1- SETUP MENU OVERVIEW 41
LEAK TEST 41
INSP/TV 41
LANGUAGES 41
VER (Version) 41
SN (Serial Number) 41
2- CALIBRATION MENU OVERVIEW 41
BATTERY 42
PRESSURE TRANSDUCER 42
FLOW CALIBRATION 42
TOUCHSCREEN (CALIBRATION) 42
KEYS (Touchscreen Test) 42
DISPLAY (LCD) TEST 42
VALVES 43
HOURS 43
FACTORY SERVICED 43

B- PERFORMANCE CHECKS 44
1- SETUP MENU 44
OXYGEN SENSOR CALIBRATION 44
LEAK TEST 44
2- CALIBRATION (CAL) MENU 44
KEYS 44
DISPLAY 44
FLOW VERIFICATION 44
FLUSH 45
POP OFF 45
3- MAIN MENU 45
BAR GRAPH ACCURACY 45
PEEP PRESSURE SIGNAL 45
BATTERY ALARM 45
EXTERNAL POWER FAILURE ALARM 45
POWER FAILURE ALARM 46
SUPPLY PRESSURE ALARM 46
ALARM QUIET 46
BACKLIGHT 46
LOCK 46
RATE 46
TIDAL VOLUME 46
SIGH 46
ALARM MENUS 46
SIMV BACKUP RATE 46
PRESSURE SUPPORT 47
PRESSURE TRIGGER 47

MANUAL 47
C- RECOMMENDED TOOLS AND TEST EQUIPMENT 48
1- Special Tools and Test Equipment 48
D- PREVENTATIVE MAINTENANCE 49
1- RECOMMENDED MAINTENANCE SCHEDULE 49
TIMELINE 49
GAS INLET FILTER 49
BATTERY CHECK 49
2-PREVENTIVE MAINTENANCE PARTS KITS 49
E-SOFTWARE UPGRADES 51
F- PNEUMATIC CALIBRATION 52
G- DISASSEMBLY & REASSEMBLY INSTRUCTIONS 59
1. REAR PANEL 59
2. BATTERY REMOVAL & REPLACEMENT 59
3. FRONT BEZEL 60
4. DISPLAY/TOUCHSCREEN 60
5. POPULATED CIRCUIT BOARD (PCB) 60
6. COMPLETE PNEUMATICS AS AN ASSEMBLY 61
7. PNEUMATIC VALVE BRACKET ASSEMBLY 62
8. FLOW, MAX PRESSURE & PEEP VALVES 63
9. SOLENOIDS 64
10. ENTRAINMENT ON/OFF SWITCH 64
11. GAS INPUT FILTER 65
12. PREVENTIVE MAINTENANCE KITS 65
H- TECHNICAL TROUBLESHOOTING CHART 66
X. PARTS LIST AND SCHEMATIC DIAGRAMS 68
A- REPLACEMENT PARTS LIST 68
B- SCHEMATICS 69
1- PNEUMATIC SCHEMATICS 69
2- PCB BLOCK DIAGRAM 71
3- CIRCUIT SCHEMATICS 72
WARRANTY 83
APPENDIX A 84
ABBREVIATIONS 84
APPENDIX B 85
DEFAULT SETTINGS 85
APPENDIX C 86
SUMMARY OF PARAMETER RANGES / ACCURACIES 86
APPENDIX D 87
SUMMARY OF DISABLED FUNCTIONS 87
APPENDIX E 88
AUDIBLE ALARM CODES 88

APPENDIX F *89*

CHARGERS AND INVERTERS **89**

APPENDIX G *90*

EUROPEAN AGENT **90**

INDEX *91*

I. PATIENT SAFETY, WARNINGS, CAUTIONS AND NOTES

The CROSSVENT-3+ ventilator is intended for use only by a qualified practitioner, under the direction of a qualified physician. All personnel operating the ventilator must be completely familiar with the warnings and operating procedures in this manual prior to using the CROSSVENT-3+ with patients. As with any life support device, the patients on the CROSSVENT-3+ should be visually monitored by competent personnel at all times since life threatening conditions may arise that may not be detected by the alarms. It is essential to test all life-support devices for proper function prior to each use on patients.

A- WARNINGS, CAUTIONS, AND NOTES

The following terms are used throughout this manual:

WARNING - Indicates a procedure or condition that could cause bodily injury.
CAUTION - Signifies a procedure or condition that could damage the equipment.
NOTE - Refers to a procedure or condition that requires special attention.

WARNINGS

- Whenever the CROSSVENT is connected to a patient, a skilled operator should be present at all times at the ventilator or within hearing range of the ventilator's alarm system.
- Only qualified medical personnel should operate the ventilator.
- Do not attempt to ventilate a patient until thoroughly familiar with all of the operating instructions.
- The operating instructions are not intended as recommended clinical protocols.
- Always test the ventilator prior to each use. After set up, ventilate a test lung to verify proper operation prior to connecting the ventilator to a patient.
- If a malfunction should occur, the unit should be removed from use and repaired prior to using it again on patients.
- Whenever an alarm condition exists it should be rectified immediately. Never allow ventilation with an alarm condition for an extended length of time.
- High oxygen concentrations may be hazardous to the patient.
- If the gas supply fails or there is a total electrical power failure, the patient may breathe atmospheric gas through the failsafe valve. This is, however, only a temporary emergency measure, which requires elevated inspiratory effort and it should be corrected immediately.
- If breathing through the negative pressure relief valve or in the case of entrainment usage, the operation of the Crossvent in a contaminated environment can be hazardous.
- Always operate the CROSSVENT on battery prior to use to confirm that the battery is functioning.
- In the event of an AC power failure, the CROSSVENT will automatically switch to battery operation and sound an alarm. The audible alarm may be silenced by pressing the POWER SOURCE key which will be flashing. On a fully charged battery, there will be approximately 6 hours of autonomous operation. No further alarm will be sounded until the battery is low. The low battery alarm may be temporarily silenced by pressing the Alarm Quiet key. It is imperative to restore AC power at this time to assure continued safe operation of the ventilator.
- A patient filter should always be used in the patient breathing circuit to prevent cross contamination.

I. PATIENT SAFETY- CONT.

- Extreme care should be taken to assure that the patient circuit components are connected correctly. Improper connection can cause malfunction.

- Periodically the CROSSVENT-3+ should be operated in the test mode to ascertain that it is functioning properly. A test lung should be ventilated prior to each use to further insure that all modes are functioning correctly. An external spirometer should be used to verify correct volumes and flow rates.

- The patient should never be left unattended after the ALARM QUIET key is depressed since this is followed by a period when the audible alarms are deactivated.

- An audible alarm always indicates an anomalous state which should always be rectified.

- While some alarms may be turned off to permit use of the CROSSVENT without them, it is recommended that they be used at all times.

- Always be certain that the Maximum Pressure Limit is set correctly and is operative even when volume limiting, to prevent possible inadvertent administration of high pressure. Increased pressure can be caused by blocked tubes, changes in patient compliance or resistance, or system malfunction.

- The alarm ports on the front of the CROSSVENT should never be obstructed.

- For proper operation only the O_2 sensor supplied by Bio-Med Devices may be used.

- Never operate the CROSSVENT-3+ without a battery since it will fail to operate if the plug-in power supply is removed.

- The screened ports on the side, back, and bottom of the unit should not be obstructed when the ventilator is in use.

- Only qualified, trained, service technicians should attempt repairs and service when needed. Serious personal injury and/or equipment damage can result if repairs are performed by unqualified personnel

- It is imperative to verify that clinically appropriate alarm limits are fully operational following connection of the ventilator to a patient.

- It is important to note that once a sensor has been turned off, the alarms for that sensor are inoperative.

- Breathing through the negative pressure relief valve requires a greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse affects to the patient.

- It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the CPAP mode.

- When in SIMV, it is important to always set a correct SIMV RATE, TIDAL VOLUME and FLOW to insure proper ventilation in case the patient becomes apneic.

- When in CPAP, it is important to always set a correct BACKUP RATE, TIDAL VOLUME and FLOW to insure proper ventilation in case the patient becomes apneic.

- To obtain the full 3-minute duration of the Power Failure alarm, the Crossvent must have been powered on for at least 1 minute.

- All safety measures must be observed when servicing this device. In particular, the ventilator must be turned off and the power supply disconnected.

- Bio-Med Devices cannot be held responsible for any failure to adhere to the recommendations set forth in this manual.

- Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

- When setting Pressure Trigger, auto-triggering or missed breaths may occur due to various conditions including, but not limited to, compliance, resistance, rate, flow, PEEP, I:E ratio, and circuit characteristics.

- Do not re-use disposable breathing circuits.

- Operation of the Crossvent in a contaminated environment can be hazardous when entrainment is used.

- It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the SIMV and CPAP modes. Also, under certain conditions in SIMV with PEEP, even though the low peak pressure alarm is set correctly for assisted breaths, there may be no low peak pressure alarm following a patient disconnect until the next assisted breath. This period may be up to 2 minutes.

- Improper changes made in the Calibration menu can be detrimental to the performance of the ventilator.

- Do not apply tension to the flow sensor (pneumotach) tubing. Do not allow the sensor to be in the patient circuit when not connected to the ventilator.

- In rare instances, when using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

CAUTIONS

- Clean, dry, medical grade gas sources supplied at 31 to 75 psi (303.6 – 517.4 kPa) unrestricted flow must be used at all times to assure proper operation of the CROSSVENT Ventilator. If an air/oxygen blender is used, then 45 – 75 PSI (310 – 517 kPa) should be supplied to the blender.

- The CROSSVENT should not be steam or gas sterilized as this will result in damage to some of its components.

- Connect the oxygen sensor (optional) upstream of the humidifier since the fuel cell functions better in non-humidified gas.

- Touchscreen control keys should be pressed by hand only. Care should be taken not to allow keys to be contacted by sharp objects as damage may result.

- Clean touchscreen only with alcohol. Clean the rest of the CROSSVENT unit with mild, non-abrasive, anti-bacterial cleanser.

- Do not place liquids on or near the CROSSVENT. Liquid entering the unit can cause severe damage and malfunction.

- It is recommended that the CROSSVENT never be left with its battery discharged as this will reduce battery life. After discharge of the battery, recharge fully before disconnecting the plug-in power supply.

- Only replace the battery pack with Bio-Med Devices part #PRT4467. Do not substitute. The cells are non-standard high capacity.

- When using an AC power source, only the power supply provided with the Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation (see Appendix F).

- Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications and standards as listed in Section III, Part B.

- Do not use in a MRI room.

- Antistatic or electrically conductive hoses or tubing should not be used.

- When it is necessary to operate the Crossvent from an AC inverter, only inverters in compliance with NEMA standards should be used (see Appendix F).

- Prior to turning the unit on for the first time, the battery must be charged fully using the included power supply.

- Do not apply tension to the flow sensor tubing. Do not allow the sensor to be in the patient circuit but not connected to the ventilator when ventilating.

- Do not allow the temperature of the battery to go above 131° F (55° C) whether the unit is on or off as this may cause damage resulting in a shorter life expectancy of the battery.

NOTES

- With entrainment on, flow accuracy from 5 - 100 lpm is ±10% or 1 lpm, whichever is greater, and with a flow of 100 lpm and over, flow accuracy is within 15% of displayed flow. No accuracy is claimed below 5 lpm.

- When the CROSSVENT is turned on, it automatically recalls all of the settings stored in memory before it was turned off. The parameters stored are: all the main functions; high and low alarm limits; secondary modes; which sensors are on or off. Several factors can cause the battery backed memory to be lost. These are: low battery backed memory battery voltage (service required); defective random access memory (service required); or if the microprocessor is, by chance, storing data in the battery backed memory at the time power is turned off. In this case it is necessary to re-enter the previously set parameters.

- The Maximum Pressure should always be set higher than PEEP in order to achieve the PEEP setting.

- While connected to an active gas source, the Maximum Pressure and PEEP controls should be turned off (fully counter clockwise) when the Crossvent is not in use to conserve gas.

- The Power Failure alarm may not be silenced using the Alarm Quiet key. The Power Failure alarm may be silenced by pressing the alarm reset button.

- Pressure Support is only active during SIMV and CPAP, but may be set at any time.

- The wall plug-in power supply is furnished for 117 VAC, 60 Hz or 220 VAC, 50 Hz operation, as required. It is not possible to overcharge the battery. Always keep the battery fully charged when not in use.

- It is important to use the correct reference gases (100 and 21%) when performing the Oxygen sensor calibration. A worn out sensor will not calibrate accurately.

- Since it is not possible to damage the CROSSVENT ventilator by normal use of its keys and control knobs, the user is encouraged to experiment with the CROSSVENT settings while the unit is not connected to a patient.

- A highlighted field on the display indicates that a parameter has been selected and may be adjusted using the arrow keys.

- If it is desired to deactivate the oxygen sensor, select it and scroll the lower limit down to OFF. The oxygen function is now inoperative. The function may be reactivated at any time by pressing it and scrolling the low limit up. The oxygen sensor is now reactivated. This allows the ventilator to be used without the oxygen sensor. When this sensor is off, it may be disconnected while the ventilator is in use, without causing an alarm.

- For blended gas, the Bio-Med Devices blender should be used.

- It is recommended that an external filter/water trap be used at all times in order to provide greater protection to the internal components of the CROSSVENT.

- For greatest accuracy, verify flow using a 60% O2 gas supply, making certain that the pressure to the CROSSVENT inlet remains within specified pressure limits (31-75 psi; 303.6 –517.4 kPa) at all flows.

- When the Crossvent is first turned on and is in battery mode, if a period longer then 60 seconds passes and the BATTERY key has not been pushed, an audible alarm will sound. When the BATTERY key is pushed, the audible alarm will be silenced.

- Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed periodically (once a month) in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

- It is not recommended that entrainment be turned on or off while ventilating. However, if this should become necessary, then it should be done during the expiratory phase of the breathing cycle. Be aware that this will change the flow.

- Approximately twenty minutes of operation will remain after a low battery alarm assuming a properly maintained battery in good condition.

- The battery should be replaced at least every two years. Only use batteries supplied by Bio-Med Devices, part #PRT4467.

- Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

- When first turned on, the unit displays "Bio-Med Devices, Inc." until the initialization process is complete. If this does not clear, submit unit for service.

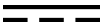
- Be aware that the SIMV rate is also the backup rate which is the rate the patient will get in the event of apnea.

- While scrolling a parameter, some hesitation may be observed.

SYMBOLS

Type BF Equipment

Date of Manufacture



Direct Current (DC)

It is essential that these instructions be read and complied with prior to operating this product.

Must be disposed of in accordance with WEEE Directive.
At the unit's "end of life", it may be returned to the manufacturer for proper reclamation.

Do not rotate the power supply plug when it is engaged with the jack.

Power On

Power Off/Valve Closed

Valve Open

II- UNPACKING AND ACCESSORIES

A- UNPACKING

CAUTION: Prior to turning the unit on for the first time, the battery must be charged fully using the included power supply.

Examine the CROSSVENT carton to ascertain whether it has sustained any damage during shipment. Inspect the contents of the shipping carton. If any damage to the product is observed, notify the carrier at once. Only you, the consignee, can make a claim against the carrier for damage in shipment..

Once the Crossvent and accessories have been removed from the packaging and passed visual inspection, place the unit in a location where it will be within reach of a standard AC outlet. Plug the separate AC power cord into the accompanying power supply and then plug this cord into the standard AC outlet. Plug the locking connector from the power supply, red dot facing to the front of the Crossvent, into the Power Connector on the left side of the unit just below the ON/OFF switch. Once plugged in, the charging LED above will begin to blink slowly (approximately once per second) indicating it is charging. (Rapid blinking indicates a problem with the charging and Technical Support should be contacted at 800-224-6633). Charge the unit until the green charging indicator stops blinking and remains solidly lit. This indicates the battery is fully charged. This may take up to five hours depending on the state of the battery when the unit was received.

Refer to the performance checks in the service section of this manual prior to placing this ventilator into service.

B- ACCESSORIES

The following is a list of the equipment supplied with the CROSSVENT-3+ Intensive Care/Transport Ventilator. Additional accessories available for the Crossvent may be found on our website at www.biomeddevices.com.

Quantity.	Cat. No.	Description
1	3300C	CROSSVENT-3+ Ventilator
1	2002K[1]	Air/Oxygen Blender
1	2013	Pole Mounting Bracket
1	1010	High Pressure Supply Hose – Oxygen
1	PFIT150[2]	DISS Male to Male Coupler
1	1011[2]	High Pressure Supply Hose - Air
1	80011	Disposable Adult Breathing Circuit
1	1020	Test Lung
1	4401	Disposable Patient Filter
1	4410[1]	Disposable Pediatric/Adult Pneumotach
1	4434	Oxygen Sensor Cell w/2.5mm Plug
1	4418	Oxygen Sensor Cell Tee
1	4414[1]	Oxygen Filter/Water Trap
1	4415[3]	Air Filter/Water Trap
1	3304C	Instruction Manual
	2120[2]	Blender Instruction Manual
1	--------	Warranty Card
1	4419A	Charger w/Cord, U.S.A. AC Adapter
1	4419B[3]	Charger w/Cord, International AC Adapter

NOTE: 1 - OPTIONAL
2 - STANDARD WITH BLENDER
3 - STANDARD WITH INTERNATIONAL ORDERS

III. SPECIFICATIONS, CONNECTIONS AND USER INTERFACE

A- GENERAL DESCRIPTION

The CROSSVENT-3+ Intensive Care/Transport Ventilator is an ultra compact, electronically controlled, time cycled, volume or pressure limited ventilator with intensive care capabilities. It provides a wide range of operating parameters to allow ventilatory support of patients from pediatric through adult. The CROSSVENT-3+ delivers the same oxygen concentration as the supply gas unless the optional entrainment is in use in which case it is a nominal 50% O_2.

The ventilator's microprocessors provide all operational functions, as well as monitoring the patient and providing alarms. It allows the user to enter many different operational and alarm parameters to accommodate a wide variety of clinical situations.

Airway pressure is sensed using an internal pressure transducer, and pressure is displayed as a bar graph on the LCD. The patient inspiratory effort is also sensed using a pressure transducer. An absolute pressure transducer monitors atmospheric pressure and automatically compensates the displayed flow for altitude changes.

Since the CROSSVENT-3+ is totally separable from a compressor and since it may be used with any 31 to 75 psi (214 – 517 kPa) psi gas source, it is extremely versatile. It may be used in most areas of the hospital and in transport. It may be mounted on a compressor, on a pedestal stand, a cart, a wall bracket, or a bed rail. It may also be mounted in vehicles such as helicopters and ambulances.

CAUTION: Do not use in a MRI room.

The CROSSVENT-3+ has an internal battery which provides power during transport and in the event of an AC power failure. If the external power should fail, the ventilator automatically switches to its internal battery and sounds an alarm. The battery operation is approximately 6 hours on a fully charged battery. If more time than that is required, the backlight may be turned off as described in this manual. Whenever external power is restored, the CROSSVENT-3+ switches back to external power operation. It will charge the battery whenever external power is available.

The CROSSVENT-3+ Ventilator's extreme reliability is made possible by:

- An absolute minimum of moving parts.
- An extremely low total parts count.

In addition to increased patient safety, the high reliability insures low downtime and thus more economical use.
The CROSSVENT-3+ provides a complete array of features and ventilatory modes and functions which include:

- Microprocessors control of all operational functions and monitoring.
- A Graphic LCD (liquid crystal display) with a touchscreen keypad, allowing the clinician to select functions just by pressing the function displayed by the LCD. This provides the friendliest and most flexible possible user interface.
- Automatic switch-over to battery backup operation.
- Auto-test mode with complete microprocessor diagnostics.
- Sensors to measure airway pressure, oxygen concentration (optional).
- Exhaled Tidal Volume and Minute Volume displays & alarms (optional).
- Displays and alarms for Peak Pressure, Rate, Mean Pressure, PEEP Pressure and Oxygen concentration and more.
- Programmability and expandability.
- Built-in triggered demand flow for minimum work of breathing during SIMV and CPAP and a simplified system design.
- Integral ASSIST CONTROL, SIMV, CPAP, PEEP, and Pressure Support functions.
- Altitude Compensation
- RS-232 input for PC interface for software updates.

B- SPECIFICATIONS

Rate	5 – 150 bpm
Inspiratory Time	0.1 – 3 seconds
Tidal Volume	5 – 2500 ml
Flow Rate	1 – 120
Inspiratory Time	0.10 – 3.0 seconds
I:E Ratio	3:1 to 1:99
Peak Pressure	0 – 120 cmH_2O
PEEP Pressure	0 - 35 cmH_2O
Pressure Trigger	-0.2 to –10 cmH_2O
Pressure Support	0 – 50 cmH_2O
SIMV Rate	0.6 – 50 bpm
Sigh	0 - 2500 ml
Maximum Safety Pressure:	120 cmH_2O
Pneumatic Power Source:	31 to 75 psi (214 – 517 kPa)[1]
Audible Alarm Characteristics:	90 dB at 10cm (25°C)

Electrical Power Source:
See Appendix F at the beginning of the manual

Output:	16.0 VDC, 3 A
Output Protection:	Short Circuit and Overload
Isolation:	Meets IEC601.1, classification BF, UL 544 Patient Care, CSA 125 Risk Class 2G
Maximum Ripple:	<100 mVp-p
Safety:	Approved to UL 544/2601.1, CLU (CSA) 22.1 #125/601.1, TUV EN60601.1 & CE LVD
EMC:	Designed to Level B Requirements of FCC part 15, CISPR11 (EN55011). Less than 1 Volt Output Deviation for IEC801-2, 3, 4, 5, Immunity Tests.

Overall Dimensions

Height:	10" (25.4 cm)
Width:	11" (28.0 cm)[2]
Depth:	5.5" (14 cm)
Weight:	10.5 lbs. (4.8 kg)[3]
Operating Temperature:	32° to 104° F. (0° to 40° C)[4]
Storage Temperature:	32° to 122° F. (0° to 50° C)[4]

1- If an air/oxygen blender is used, then 45 – 75 PSI (310 – 517 kPa) should be supplied to the blender.
2- 14.25" (36.2 cm) with optional mounted blender
3- 13.25 lbs. (6 kg) with optional mounted blender
4- When using the oxygen sensor, then 41° – 104° F (5° – 40° C); battery will not fast charge below 41° F (5° C) nor above 125° F (51° C).

C- MANUAL CONTROLS AND CONNECTIONS

1- FRONT OF VENTILATOR

FLOW CONTROL KNOB

Adjusting this knob sets the inspiratory flow from 0 - 120 lpm. The Flow setting is displayed in the FLOW key on the display. It is accurate from 1 to 120 lpm.

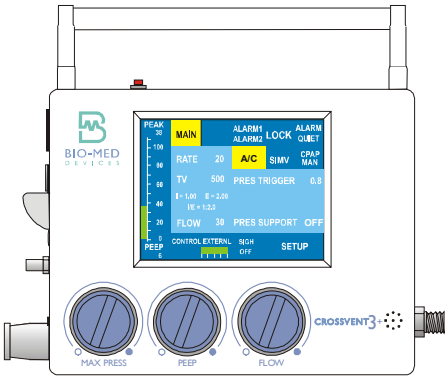


FIG. 1- FRONT VIEW

WARNING: In rare instances, when using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

NOTE: With the optional entrainment on, flow accuracy from 5 - 100 LPM is ±10% or 1 LPM, whichever is greater, and with a flow of 100 LPM and over, flow accuracy is within 15% of displayed flow. No accuracy is claimed below 5 LPM.

When air entrainment is on, verify the message "ENTRN" is displayed in the Inspiratory Source Key.

Set the FLOW after entrainment is turned on since the flow calibration is automatically adjusted for entrainment. It is not recommended that entrainment be turned on or off while ventilating. However, if this should become necessary, then it should be done during the expiratory phase of the breathing cycle. Be aware that this will change the flow.

MAXIMUM PRESSURE KNOB

Adjusting this knob sets the pressure applied to the exhalation valve and to an internal adjustable relief valve. This determines the maximum pressure during assisted and controlled inspirations. It is adjustable from 0 - 120 cmH_2O. It should always be operative and properly adjusted.

NOTE: While connected to an active gas source, the Maximum Pressure control should be turned off (fully counter clockwise) when the Crossvent is not in use to conserve gas.

PEEP KNOB

(Positive End Expiratory Pressure)- Adjusting this knob sets the PEEP or CPAP (Continuous Positive Airway Pressure) level applied to the exhalation valve. It is adjustable from 0- 35 cmH_2O. The PEEP level is determined by observing the system pressure bar graph or with the PEEP/CPAP readout on the secondary alarm menu.

NOTE: The Maximum Pressure should always be set higher than PEEP in order to achieve the PEEP setting.

NOTE: While connected to an active gas source, the PEEP control should be turned off (fully counter clockwise) when the Crossvent is not in use to conserve gas.

AUDIBLE ALARM

Located next to the BMD logo on the front of the unit, it emits the audible tones to indicate an alarm condition or keyboard actuation.

WARNING: It should never be obstructed.

NOTE: Refer to Appendix E for all the beeper codes.

ALARM LED

This flashes on and off in equal duration during any alarm providing 360-degree visibility. When unit is turned off or loses power, it flashes for 3 minutes. This time may be less if the Crossvent was not powered on for at least 1 minute prior to loss of power.

2- RIGHT SIDE OF VENTILATOR

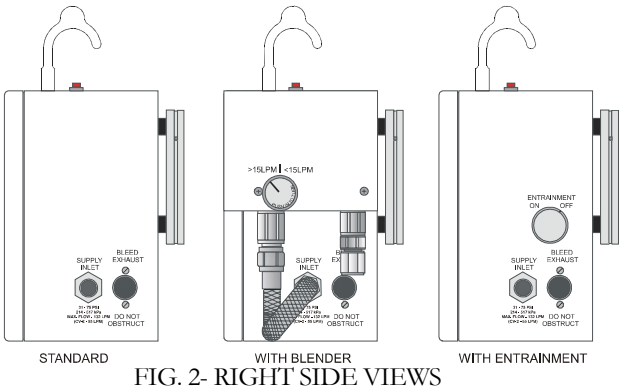


FIG. 2- RIGHT SIDE VIEWS

CAUTION: Antistatic or electrically conductive hoses or tubing should not be used.

GAS SUPPLY INLET

Male DISS 9/16-18 fitting. Clean, dry, medical grade gas, delivered at 31 to 75 psi (214 – 517 kPa) pressure at 132 lpm is required. These requirements apply to the inlet of the ventilator in order to ensure proper flows. If the supply pressure falls below 31 psi, an internal sensor will detect this and the Crossvent will alarm. A serviceable 40-micron filter is contained within the supply fitting.

GAS SUPPLY WITH BLENDER

When using a blender, oxygen and air supplies are connected to the blender and the output of the blender is then connected to the Crossvent Supply Inlet. For optimum performance, 45 – 75 PSI (310 – 517 kPa) should be supplied to the blender. Oxygen concentrations set by the blender are then delivered to the patient. Refer to the Blender Operation Manual for instruction on its use.

GAS SUPPLY WITH ENTRAINMENT

When equipped with the optional Air Entrainment Module, the CROSSVENT is able to supply either 100% or 50% (nominal) oxygen during transport, without the use of compressed air. A unique feature of the entrainment system is the ability to deliver repeatable volumes during volume limited ventilation, with relatively constant oxygen concentration.

When using entrainment, the source gas should be 100% O_2. When the air entrainment control on the right side of the CROSSVENT is turned to the ON position, a sophisticated, multiple venturi system is activated, which draws in ambient air and dilutes the 100% O2 supply gas to a nominal 50% concentration.

An additional advantage of using entrainment is that the oxygen supply consumption will be reduced, thereby increasing the operating time on a given supply of gas.

When entrainment is off, the gas delivered is the same as is connected to the supply inlet.

WARNING: Operation of the Crossvent in a contaminated environment can be hazardous when entrainment is used.

BLEED EXHAUST

Internal bleeds from the pneumatic controls exhaust through this screened port. This area must not be obstructed when the ventilator is in use.

3- LEFT SIDE OF VENTILATOR

POWER ON/OFF SWITCH

It is located on the left side of the unit and is recessed in order to reduce inadvertent or unauthorized use. It controls the main power to the electronics. If the battery is allowed to fall below 6 volts (well below the Low Battery alarm limit) with the unit operating, the ventilator will turn off independently of this switch. If this occurs, this switch must be turned to OFF before the ventilator will operate again, regardless of power source.

WARNING: Never use the On/Off switch to silence the alarms since this renders the alarms permanently disabled.

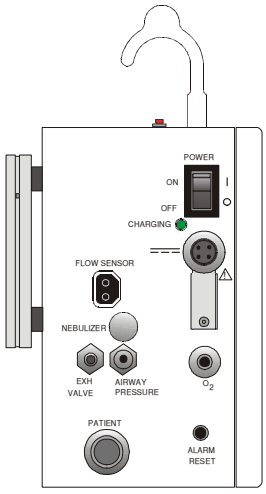


FIG. 3- LEFT SIDE

EXTERNAL ELECTRICAL SUPPLY CONNECTOR

This receptacle accepts the plug from the factory supplied, U.L. approved, power supply module. The plug and receptacle are keyed so they will only go together when the red dot on the plug faces to the front of the unit and the cord is within the two arms of the guard. By necessity, this power supply meets all the specifications and standards listed in Section III, Part B. Use only Jerome Industries model WSZ116M (16VDC, 3A) with the appropriate mating plug. The Crossvent should not be used with any other wall plug-in or desktop AC adapter. This is used to operate the ventilator and to charge the battery whenever it is below full charge. The wall plug-in power supply is furnished for 117 VAC, 60 Hz or 220 VAC, 50 Hz operation, as required. It is not possible to overcharge the battery. Always keep the battery fully charged when not in use.

CAUTION: Do NOT attempt to rotate the power connector while it is plugged into the ventilator. It must only be pushed straight in and pulled straight out.

CAUTION: When using an AC power source, only the power supply provided with the Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation.

CAUTION: Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications and standards as listed in Section III, Part B.

CAUTION: When it is necessary to operate the Crossvent from an AC inverter, only inverters in compliance with NEMA standards should be used (see Appendix F).

CHARGING LED & BATTERY

The Charging LED indicates the charging mode when the external power supply is plugged into the Crossvent. Its states are:

1. Slow Blinking (approximately once per second)- unit is in rapid charge mode.
2. Rapid Blinking- failure in the charging system or the temperature of the battery was above 125°F (40°C) when the external power supply was connected.
3. On Steady- trickle charge mode.

The battery operation is approximately 6 hours on a fully charged battery. Turning off the backlight can extend this time (refer to Backlight in Part D of this section).

To charge the battery, only the power supply provided by Bio-Med Devices should be used. With the red dot on the supply's connector facing the front of the Crossvent, plug the external power supply into the side of the unit and into an AC outlet. Charge the battery until the charging LED indicates it is in trickle charge mode and the battery is fully charged (solid LED). The amount of time required to fully charge the battery depends on many factors, including the state of charge when it begins. The maximum time for an exhausted battery is approximately 5 hours. When done, verify battery power by unplugging the external power cord from the side of the unit while it is turned on. The Crossvent should alarm and the power source key at the bottom of the display should flash "BATT". Press this key to cancel this alarm. The battery bar indicating the remaining battery power should span the entire battery key unless the battery was fully discharged, in which case it may only indicate 90%. This condition will self-correct with further charging cycles.

If the temperature of the battery is over 125°F (51°C), it cannot accept a charge. This situation should be avoided. If the battery reaches this temperature during a rapid charge, it will go into trickle charge mode until it is below this temperature.

CAUTION: Do not allow the temperature of the battery to go above 131° F (55° C) whether the unit is on or off as this may cause damage resulting in a shorter life expectancy of the battery.

When the state of the battery is determined to be within approximately 20 minutes of remaining autonomous operation, the Alarm 3 menu will flash "LOW BATTERY, CONNECT EXTERNAL POWER" and sound the audible alarm. The ventilator should be switched to external power or removed from service and recharged when this alarm occurs. If the battery is allowed to expend energy to a point below 6 volts (well below the Low Battery alarm limit), the ventilator will shut down independent of the On/Off switch. If this occurs, the external power supply must be used to recharge the battery and the On/Off switch must be turned to Off and then back to On before the unit will operate.

NOTE: 20 minutes of operation after the low battery alarm assumes a properly maintained battery in good condition.

The NiMH rechargeable battery is located internally and should only be accessed by trained service personnel. To prolong life and maintain performance, it is recommended that the Crossvent be stored with the power supply plugged in or with the battery fully charged at a relative humidity of 65% (±20%)

whenever possible. Because NiMH batteries will naturally "self-discharge", it is strongly recommended the battery be cycled through at least one charge/discharge according to the table below if left off the power supply for an extended period of time.

Storage Temperature Range	Time to Charge/Discharge
104°F to 122°F (40°C to 50°C)	Less than 30 Days
86°F to 103°F (30°C to 39°C)	30 to 60 Days
32°F to 85°F (0°C to 29°C)	61 to 90 Days

WARNING: Never operate the CROSSVENT without a battery since it will fail to operate if the plug-in power supply is removed.

CAUTION: The battery should be replaced at least every two years. Only use batteries supplied by Bio-Med Devices, part #PRT4467. Do not substitute.

FLOW SENSOR (PNEUMOTACH)

The pneumotach (use is optional) plugs in here and permits the measurement of flow, which is used to display Exhaled Tidal (or Minute) Volume. Only the pediatric/adult pneumotach can be used with this ventilator. If any other pneumotach is plugged in, a warning will be displayed in the Alarm 1 menu.

CAUTION: Do not apply tension to the flow sensor tubing. Do not allow the sensor to be in the patient circuit but not connected to the ventilator when ventilating.

CAUTION: The pressure connection tubes of the pneumotach should always be mounted vertically to prevent collection of condensate in the pressure tubes. The tubes should be inspected periodically and condensate should be removed. This condensate may cause erroneous readings and thus improper operation of the CROSSVENT. Never block these connections with the unit operating as this can damage the internal transducer. Always securely connect the pneumotach to its connector before inserting the pneumotach in the flow stream. This will prevent possible damage to the internal transducer and will also prevent humidified gas from inadvertently blowing up the pneumotach sensing lines.

OXYGEN SENSOR CONNECTOR

O_2 sensor (use is optional) plugs in here. This measures the oxygen concentration of the gas mixture being delivered to the patient and is displayed in the Alarm 2 menu.

WARNING: For proper operation, only the O_2 sensor supplied by Bio-Med Devices may be used.

EXHALATION VALVE CONNECTOR

The tube to the exhalation valve on the patient circuit connects here and provides the pressure signal to operate the exhalation valve. During inspiration it applies a pressure signal to the exhalation valve diaphragm which sets the Maximum Pressure Limit. During expiration it provides zero or PEEP/CPAP level pressure to the exhalation valve diaphragm.

AIRWAY PRESSURE CONNECTOR

The proximal airway pressure tube on the patient circuit connects here. This allows the CROSSVENT to monitor airway pressure and also to detect patient inspiratory efforts.

PATIENT GAS CONNECTOR

The main patient corrugated hose is attached here. It provides the un-humidified breathing gas mixture to the patient circuit.

ALARM RESET SWITCH

Pressing this button silences the alarm of the Power Failure circuit, which is a separate section of the main circuit board.

This circuit monitors the power to the main circuit board. If power is lost, either as a result of turning the main power switch off or a total power failure to the circuit board, i.e., no external power and no battery, it sounds an audible alarm (long tone) and flashes the LED, which will continue for at least 3 minutes after failure. Pressing the Alarm Reset Switch permanently silences the audible alarm.

WARNING: To obtain the full 3-minute duration of the Power Failure alarm when power is lost, the Crossvent must have been powered on for at least 1 minute prior to the failure.

4- REAR OF VENTILATOR

MAXIMUM PRESSURE RELIEF VALVE

A preset, relief valve exhausts through the rear of the unit. This valve establishes the maximum safety pressure deliverable. It is set at 120 cmH_2O.

WARNING: It should never be obstructed.

NEGATIVE PRESSURE RELIEF VALVE

The inlet for a preset, negative pressure valve is located in the rear of the unit. It allows the patient to breath ambient air if the entire system should become inoperative. It opens at approximately -4 cmH_2O.

WARNING: It should never be obstructed.

WARNING: Breathing through this valve requires a greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse affects to the patient.

WARNING: Should the use of the negative pressure relief valve become necessary, the operation of the Crossvent in a contaminated environment can be hazardous.

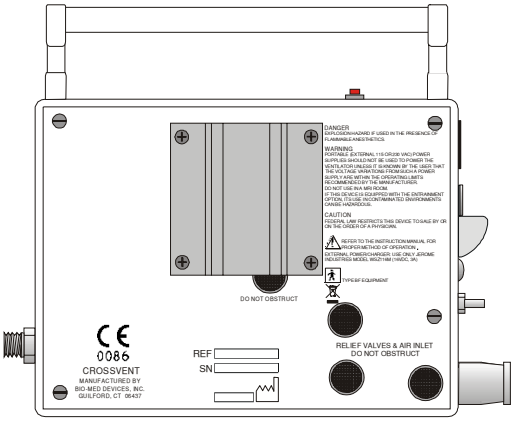


FIG. 4- REAR VIEW

CE MARK

The CE mark displayed on this product signifies that this device is in compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.

EU Classification:

Internally-powered equipment
Continuous operation
BF type applied part
Not suitable for AP or APG

D- DISPLAY INTERFACE AND MENUS

1- DISPLAY OVERVIEW

Careful attention has been paid to the human interface of the CROSSVENT. Its Graphic LCD, with touchscreen keypad, makes it the most user-friendly ventilator for today and tomorrow. Several menus are available on the LCD. These include: Main functions, Primary Alarms, Secondary Alarms and a Setup menu.

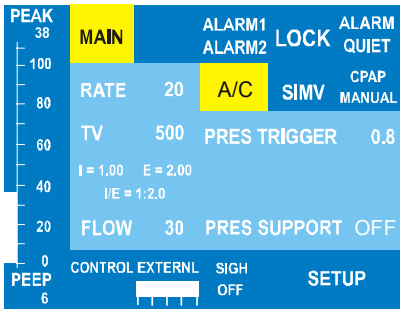


FIG. 5- SETUP KEY

NOTE: When first turned on, the unit ***displays "Bio-Med Devices, Inc."*** *until the initialization process is complete. If this does not clear, submit the unit for service.*

SELECT AND ADJUST A FUNCTION

A menu or parameter is selected by simply pressing the corresponding key on the display. In this manual, when references are made to keys, this is an area of the display containing text or values. There may not always be a "key" depicted graphically. When instructed to press a key, it implies to press on the touchscreen over the word or value you want to select. When a function is selected, the function will be highlighted in yellow.
Once a parameter is selected it may be adjusted using the UP and DOWN Arrow keys. The parameter key may be pressed again to deselect it. If the arrow keys are not pressed for 30 sec., the highlighted key will automatically deactivate. The following are exceptions to the procedure for setting functions:

- Arrows are not required to select a menu or mode. These are selected simply by pressing the desired key, i.e. ASSIST CONTROL.
- Flow is displayed in the Flow key, but may only be changed with the FLOW Control Knob.
- I, E, I/E ratio is a display key only. I, E, I/E are set indirectly by setting Rate, Tidal Volume and Flow.

The display is graphically laid out for simplicity and ease of use. The left side of the display indicates Airway Pressure information. The top and bottom rows of keys are always available to the user unless Setup is pressed. The top row allows the user to move between menus as well as lock the display and quiet the alarms. The bottom row provides information on what type of breath is being delivered, power conditions as well as allowing for sigh and entering SETUP. SETUP is replaced by the ARROW keys by pressing any key other than the ALARM QUIET or BATTERY key or if no key is pressed within 30 seconds of powering on the unit.. The center section of the display is what is considered the "menu" and is the part that changes when a menu key is pressed.
What follows will describe in detail the function of each key.

2- BACKLIGHT& PRESSURE BAR GRAPH

AIRWAY PRESSURE BAR GRAPH

Displayed on the left side of the display is an analog readout of proximal airway pressure from -5 to +115 cmH_2O. As the airway pressure increase, a green bar rises to reflect the pressure. If the pressure exceeds the setting of the Peak High Pressure limit in the Alarm 1 menu, then the portion of this bar above the limit will be red. When the pressure bar goes below zero, it will be yellow. Above and below the bar graph are numerical values for PEAK and PEEP/CPAP pressures respectively. The PEAK display at the top should be used for readings when the pressure exceeds the range of the bar graph.

BACKLIGHT

The LCD display requires a backlight in order to be visible. Therefore, the default setting for the backlight is that it is always on. There may be circumstances in which the user may desire the backlight to be off (ie., to extend the running time while in battery mode). However, be aware that turning off the backlight means there is no visible display. It will be completely blank. To turn off the display, press and hold the Pressure Bar Graph for 3 seconds until it beeps a second time. The backlight will remain off until an alarm condition occurs or the display is touched. When the unit is powered off, it will revert to the default of always being on.

3- MAIN MENU

Pressing the MAIN key displays the Main menu. When in the Main menu, ventilation modalities, Assist Control, SIMV, or CPAP, may be selected. The selected mode will be highlighted and it becomes immediately operative.

Ventilation modes:

ASSIST CONTROL (A/C)

Provides controlled or assist/control ventilation depending upon the Pressure Trigger setting (see below). If the patient fails to initiate an inspiration, the CROSSVENT will continue to cycle at the respiratory rate set with the RATE control.

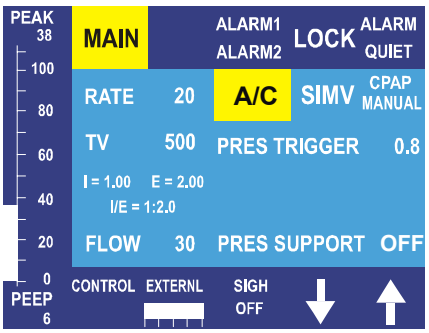


FIG. 6- MAIN MENU

SIMV

(Synchronized Intermittent Mandatory Ventilation) mode - Provides spontaneous and intermittent assisted breaths. The unit will respond to the patient's initiation of spontaneous breaths according to the PRESSURE TRIGGER setting (see below). A breath will be delivered at a flow rate set with the FLOW control and for the length of time of a normal inspiration as set with the TIDAL VOLUME (or INSP setting, if available). During these spontaneous breaths, a bolus of gas flows to the patient at PEEP or atmospheric pressure. The patient inspires the amount desired and the rest is passed through the exhalation valve to atmosphere. At intervals set with the SIMV RATE, a triggered breath is provided under pressure (synchronized mandatory breath). If the patient's rate falls below the set SIMV Rate, the Crossvent will deliver pressurized back-up breaths at the set SIMV rate.

CPAP

(Continuous Positive Airway Pressure)/Manual mode - Provides spontaneous breaths at PEEP or atmospheric pressure (see spontaneous breaths under SIMV above). The MANUAL function is operative in this mode.

WARNING: It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the CPAP mode.

WARNING: Under certain conditions in CPAP, in particular with high flows and low CPAP pressures, if the low peak pressure alarm is set so that no false alarms occur, this alarm may be inoperative if a disconnect occurs.

MANUAL

Operative only in the CPAP mode. Provides one normal controlled breath each time it is pressed, providing an inspiratory time and tidal volume as established by the Tidal Volume (or INSP time) and Flow controls. The minimum expiratory time allowed is 0.2 seconds. This is controlled by the software which means it will only be active in 0.2-second intervals or greater.

PRESSURE TRIGGER

Sets the trigger level below baseline (PEEP or atmospheric) at which an inspiration is initiated. It automatically adjusts for the PEEP level. It is functional in all modes and must be set for use during assisted and spontaneous breaths. It may be set to sense negative pressure changes from 10 cmH_2O to 0.2 cmH_2O below baseline. It should be set after setting the flow and may need to be readjusted if the flow setting is changed.

WARNING: When setting Pressure Trigger, auto-triggering or missed breaths may occur due to various conditions including, but not limited to compliance, resistance, rate, flow, PEEP, I:E ratio, and circuit characteristics.

WARNINGS: It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the SIMV and CPAP modes. Also, under certain conditions in SIMV with PEEP, even though the low peak pressure alarm is set correctly for assisted breaths, there may be no low peak pressure alarm following a patient disconnect until the next assisted breath. This period may be up to 2 minutes.

PRESSURE SUPPORT

May be set from 1 to 50 cmH_2O above baseline or to Off by selecting it and using the UP and DOWN Arrows. When pressure support is on, it pressurizes spontaneous breaths up to the pressure support setting. When this pressure is achieved, the exhalation valve is allowed to return to baseline pressure, but flow remains on for the duration of a normal assisted breath as set by the TIDAL VOLUME (or INSP, if available) control.

NOTE: Pressure Support is only active during SIMV and CPAP, but may be set at any time.

RATE

Sets the normal respiration rate. It is adjustable from 5 to 150 bpm, which is changed using the arrow keys. When in SIMV, this changes to SIMV RATE and when in CPAP, to BACKUP RATE.

SIMV RATE

When in SIMV mode, the RATE key becomes the SIMV RATE key. It sets the rate at which assisted breaths are given in the SIMV mode. It may be set from 0.6 to 50 bpm, which is changed using the arrow keys. This rate is also the backup rate in the event of apnea.

WARNING: When in SIMV, it is important to always set a correct SIMV RATE, TIDAL VOLUME and FLOW to insure proper ventilation in case the patient becomes apneic.

BACKUP RATE

Sets the rate at which backup breaths are delivered when in CPAP mode in the event of apnea.

WARNING: When in CPAP, it is important to always set a correct BACKUP RATE, TIDAL VOLUME and FLOW to insure proper ventilation in case the patient becomes apneic.

TIDAL VOLUME (TV)

Sets the volume of gas delivered during assisted or controlled inspirations. It is adjustable from 5 to 2500 ml, which is changed using the arrow keys. It is accurate from 50 to 2500 ml. This key may be changed to set inspiratory time rather than tidal volume in the SETUP menu. The Setup Menu is accessible only after turning the unit on, but before pressing any other key. Press the Setup key and then press TV/INSP. The currently preferred parameter, Tidal Volume in this case, is will be highlighted. Press INSP TIME if you want to set an inspiratory time rather than tidal volume. Return to the Main Menu by pressing the Setup Menu key and then the Main Menu key twice. INSP will now be displayed where TV was.

INSP

Sets the inspiratory time. It may be set from 0.1 – 3 seconds. This key may be changed to set tidal volume rather than inspiratory time by selecting TV in the SETUP menu. The Setup Menu is accessible only after turning the unit on, but before pressing any other key . Press the Setup key and then press TV/INSP. The currently preferred parameter, INSP TIME in this case, is will be highlighted. Press TIDAL VOLUME if you want to set a tidal volume rather than inspiratory time. Return to the Main Menu by pressing the Setup Menu key and then the Main Menu key twice. TV will now be displayed where INSP had been.

I, E, I/E KEY

This is a display key for informational purposes only. It cannot be used to set any parameter, but rather is used to display the corresponding inspiratory time, expiratory time and I:E ratio that result from setting the Rate, Tidal Volume (or INSP, if available) and Flow. When INSP replaces TV in the key above, as explained in the section defining the Tidal Volume key, then TV (Tidal Volume) is displayed here rather than Inspiratory time. Segments of this key will indicate alarm conditions as defined in the ALARMS section of this manual.

FLOW KEY

Displays the inspiratory flow that is set with the Flow control knob. Because the software uses a separate calibrated table for entrainment flow, this value will change when entrainment is turned on and off. If tidal volume is set in the key above this, then changing the flow will change the inspiratory time by necessity to maintain the same tidal volume. This, in turn, will also change the I:E since the rate is also fixed. Conversely, if inspiratory time is set rather than TV, then changing the flow will change the tidal volume accordingly. In this case, however, the I:E remains constant because both inspiratory and rate are fixed.

WARNING: In rare instances, when using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

4- ALARM MENUS

ALARM MENU KEY

Although there are three Alarm screens, only Alarm 1 and Alarm 2 are accessible by pressing a corresponding key. The Alarm 3 screen only appears when a specific condition, as explained later in this section, occurs. The Alarm 1 and Alarm 2 menus are available through a shared key. To access these alarm menus, press the ALARM 1/ALARM 2 key once for ALARM 1 and press it again for ALARM 2. Whichever alarm menu is currently displayed is indicated by the corresponding half of the ALARM1/ALARM2 being highlighted. When an alarm menu is displayed, pressing the ALARM1/ALARM2 key will display the other alarm menu.

When an alarm condition occurs, the appropriate alarm menu will automatically be displayed, unless it occurs while a parameter is being scrolled or if ALARM QUIET was activated with no alarm condition occurring. To change menus during an alarm condition, Alarm Quiet must be activated (see ALARM QUIET).

FIG. 7- ALARM MENUS

HIGH and LOW Alarm Limits- The high or low limits of an alarm parameter may be selected by pressing the corresponding key for that value. The value is changed using the UP and DOWN Arrows. The low limit may not be equal to nor above the high limit and vice versa. When an alarm sounds, the alarm parameter that is in violation will flash red. If more than one alarm sounds simultaneously, they each flash. Whenever an alarm is active in another menu while the Alarm Quiet is active, the corresponding menu key(s) flashes. If more than one alarm sounds simultaneously, they each flash. If alarms occur in more than one menu, the menus are prioritized. The CROSSVENT shifts first to the Alarm 1 menu and when these alarms are rectified, it shifts to the Alarm 2 menu.

NOTE: Pressing Alarm Quiet allows control of the keyboard while alarms are active.

MONITORED ALARM VALUE- the actual monitored value for an alarm is displayed in the center column between the high and low limits for that alarm.

PRIMARY ALARM MENU (ALARM1)- monitored parameters and alarms- Standard Alarms are Peak Pressure and Rate. Alarms that can be turned off are Exhaled Tidal Volume and Exhaled Minute Volume.

SECONDARY ALARM MENU (ALARM2)- monitored parameters and alarms- PEEP and CPAP, Mean Pressure, O_2. The last two may be turned off.

TERTIARY ALARMS (ALARM3)- these alarms are not displayed in a menu, but rather only as they occur. Therefore, there is no menu key. The monitored parameters and alarms are- Low Battery, Low Gas Supply Pressure, and Ventilator Failure. These messages can be displayed singularly or in any combination.

ALARM PARAMETER RANGES AND ALARM LIMITS			
PARAMETER	DISPLAY RANGE	SET LIMITS	
		LOW	HIGH
Peak Pressure cmH_2O	0-125	3-124	4-125
Rate bpm	0-199	4-159	5-160
Exh. Tidal Volume ml	50-4000	50-3199	51-3200
Exh. Min. Volume L	0-200	0.0-99	0.1-100

ALARM PARAMETER RANGES AND ALARM LIMITS			
PARAMETER	DISPLAY RANGE	SET LIMITS	
		LOW	HIGH
PEEP/CPAP cmH_2O	0-99	-1 to 99	0-100
Mean Pressure cmH_2O	0-125	0-124	1-125
O_2	0-100	18-100	19-105

ADDITIONAL ALARMS OUTSIDE OF THE ALARM MENUS	
CONDITION	INDICATED BY FLASHING[1]
INSPIRATORY < 0.1 SEC., > 3.0 SEC	INSPIRATORY DISPLAY
EXPIRATORY < 0.2 SEC.	EXPIRATORY DISPLAY
I/E > 3:1 or > 1:99	I/E DISPLAY
T_I + FLOW = TV >2500 ml	TV DISPLAY
NO EXTERNAL POWER	BATTERY KEY
LOSS OF POWER	LED
MICROPROCESSOR COMMUNICATION ERROR[2]	LED

[1] audible alarm accompanies any flashing alarm
[2] see Appendix E for beeper codes

ALARM 3

This menu displays the conditions shown in the table below. When flashing the "VENTILATOR FAILURE" message on the display, the associated audible tones may be used to identify which solenoid has failed:

MESSAGE	FAILED COMPONENT	AUDIBLE SEQUENCE	
LOW BATTERY, CONNECT EXTERNAL POWER	N/A	1 LONG	—
LOW SUPPLY PRESSURE	N/A	1 LONG	—
VENTILATOR FAILURE	SOLENOID A	1 LONG, 1 SHORT	— •
VENTILATOR FAILURE	SOLENOID B	1 LONG, 2 SHORT	— ••
VENTILATOR FAILURE	SOLENOID D1	2 LONG, 1 SHORT	— — •
VENTILATOR FAILURE	SOLENOID D2	2 LONG, 2 SHORT	— — ••
VENTILATOR FAILURE	SOLENOID D3	2 LONG, 3 SHORT	— — •••
VENTILATOR FAILURE	PNEUMOTACH TRANSDUCER	1 LONG	—

NOTE: For a full list of beeper codes, see Appendix E.

NOTES REGARDING ALARMS

RATE- The monitored rate is calculated and displayed as a rolling average over 5 breaths.

HIGH PEAK PRESSURE- Inspiratory is terminated if the peak pressure reaches the high limit as set except for sigh breaths. During sigh breaths the high peak pressure limit is increased by 1.5 times the display setting (up to 125 cmH_2O).

LOW PEAK PRESSURE- This alarm is inactive during spontaneous and CPAP breaths.

EXHALED TIDAL VOLUME (use is optional)- Exhaled Tidal Volume and Exhaled Minute Volume share the same line in the ALARM 1 menu. Therefore, only one or the other may be displayed at any given time. To display one or the other, press either EXHTV or EXHMV, depending on which is currently displayed, and press either arrow key. Repeatedly pressing an arrow key will toggle between EXHTV and EXHMV. Once the desired parameter is displayed, it becomes the active alarm and may be turned on and its limits set in the normal manner. The state of each of these parameters, either on or off, remains in effect whether it is displayed or not. Therefore, EXHTV or EXHMV may be on, but not displayed. It must be displayed, however, to be active for alarms.
The displayed Exhaled Tidal Volume updates with each breath.
Only the pediatric/adult pneumotach, #4410, can be used. Any other pneumotach will display "WRONG PNEUMO" between the high and low limits and the unit will alarm.
If there is no pneumotach plugged into the unit and either the EXHTV or EXHMV function is turned on and active, the unit will alarm and display "NO PNEUMO" between the high and low limits.
Under certain circumstances, such as incompliant or large patients, the Peak Expiratory Flow may be too great for the pneumotach to read. When this occurs, "EXCEEDS PEF" will be displayed in the Alarm 1 menu under EXHTV or EXHMV and the Crossvent will alarm. This alarm will occur even if the EXHTV or EXHMV alarm is turned off. This is to notify the user that the pneumotach may be too great a restriction in the circuit for the patient.

EXHALED MINUTE VOLUME- (see EXHALED TIDAL VOLUME)

NOTE: EXHMV indicates a projected or anticipated minute volume based on the current exhaled tidal volume readings.

PEEP/CPAP- displays CPAP when in CPAP mode and PEEP in other modes. PEEP displays an average of the previous three breaths in other modes.

DEACTIVATING ALARMS- The alarms for Mean, Exhaled Tidal Volume, Exhaled Minute Volume and O_2 may be turned off by scrolling the low limit down past its lowest limit to Off.

WARNING: It is important to note that once a sensor has been turned off, the alarms for that sensor are inoperative.

WARNING: While some alarms may be turned off to permit use of the Crossvent without them, it is recommended that they be used at all times.

5- KEYS COMMON TO ALL MENUS

LOCK

Locks all keys, except ALARM QUIET and the MENU keys, making them inactive if pressed. When active, this key is highlighted and the touchscreen is locked. To unlock it, press this key once, then press it again within 5 seconds.

ALARM QUIET

Silences the audible alarm for a period of 60 seconds or 120 seconds if pressed twice consecutively. When set, the key is highlighted and counts down showing the time remaining for which the alarms will be silenced. If it is active and the count is less than 60 seconds, pressing it once will reset it to 120 seconds. To cancel, press the key once if the time remaining is $\geq$61 seconds or twice if it is $\leq$60 seconds. When you turn the ventilator on or return to the MAIN menu from either the SETUP or CAL menus, the Alarm Quiet is activated automatically for 60 sec.

During an alarm condition, the only way to display a menu other than the alarming menu is to activate Alarm Quiet. Any menu can then be displayed by pressing its corresponding key.

When activated, the ALARM QUIET function will silence the audible alarm for any alarm conditions that exist at the time it is activated. Should a new and different alarm condition occur while it is activated,

ALARM QUIET will automatically be canceled and the audible alarm will return. If Alarm Quiet is pressed with no alarm conditions existing at the time, then any new alarm will be silenced while it is active.

ARROW KEYS

These are used to scroll up and down, at an accelerating rate, any numerical parameter that is selected and highlighted. When the value being changed reaches its upper or lower limit as allowed by the software, it stops scrolling and a tone sounds.

NOTE: While scrolling, some hesitation may be observed.

SIGH

Press this key to activate SIGH. It will change from SIGH OFF to SIGH ON. Beginning with the next breath after activation, one sigh breath is provided for every 100 normal breaths or one every 7 minutes, whichever occurs first. The tidal volume for this breath is equal to 1.5 times the normal tidal volume. This is accomplished by increasing inspiratory time for that breath. There is a tidal volume cap of 2500 ml and an inspiratory cap of 3 seconds for sigh breaths. The expiratory time following a sigh is also increased to maintain the same I/E ratio as a normal breath. Each time a sigh breath is delivered, "SIGH BREATH" is displayed in this key. Sigh is operative only in the Assist Control and SIMV modes.

POWER SOURCE KEY

This key indicates whether the unit is operating on external or battery power.

EXTERNAL POWER- Displays "EXTERNL" whenever external power is connected to the CROSSVENT-3+.

BATTERY OPERATION- Displays "BATT" when operating on battery. Flashes "BATT" whenever external power is lost and the CROSSVENT shifts to battery power. When this happens, a simultaneous audible alarm sounds which **may be silenced only by pressing this key**. Restoration of external power will automatically switch the unit back to external power operation and charging of the battery will commence. Charging will continue until a full charge is reached.

Whenever the CROSSVENT is powered on without external power, the Power Source key will alarm alerting the user the unit is operating on battery power. This alarm will continue until the user acknowledges this by pressing the flashing "BATT" key.

The Power Source key also displays a graphical representation of battery life remaining. It reduces in 2% increments as the battery power is depleted.

WARNING: Always operate the CROSSVENT on battery prior to use to confirm that the battery is functioning.

CAUTION: It is recommended that the CROSSVENT never be left with its battery discharged as this will reduce battery life. After discharge of the battery, recharge fully before disconnecting the plug-in power supply whenever possible.

NOTE: For more on the battery, refer to Section III, Part C-3.

INSPIRATORY SOURCE KEY

This key, which is next to the Power Source key, displays the type of breath being delivered during inspiratory.

SPONTANEOUS BREATH- Displays SPONT whenever an inspiration is initiated by the patient's spontaneous effort during SIMV or CPAP, delivered at PEEP or atmospheric pressure or pressurized when pressure support is on.

ASSISTED BREATH- Displays ASSIST whenever an inspiration is initiated by the patient's spontaneous efforts and delivered under pressure (volume or pressure limited breath) during Assist Control and SIMV breaths.

CONTROLLED BREATH- Displays CONTROL whenever an inspiration is initiated by the ventilator's timer (volume or pressure limited breath), during Assist Control, SIMV backup and CPAP backup breaths.

MANUAL BREATH- Displays MANUAL whenever a manual breath is delivered by pressing the MANUAL key in CPAP mode.

ENTRAINMENT ON- Below the type of breath being delivered, "ENTRN" is displayed when entrainment is on. This is displayed continuously as long as entrainment is on.

SETUP KEY

This key is only accessible immediately after powering on the unit. Pressing it will display the SETUP menu which allows the user to make changes to the unit's setup as well as calibrate the oxygen sensor (see setup procedures in Section V). It is deactivated and replaced by the ARROW keys by pressing any key other than the ALARM QUIET or BATTERY key or if no key is pressed within 30 seconds of powering on the unit.

CALIBRATION- This menu is accessed from the SETUP menu. It is reserved for maintenance procedures for service personnel.

IV. SETUP AND OPERATING INSTRUCTIONS

A- INSTALLATION

1. MOUNTING OPTIONS

The CROSSVENT Ventilator may be mounted in several different ways depending on the clinical application and surroundings. It may be placed on a tabletop or mounted on a compressor, or a pedestal stand, using its pole mount bracket on the back of the ventilator. This bracket will also accommodate the pole of a wall mount adapter to permit the CROSSVENT to be mounted off the floor.

This equipment has been tested and found to comply with the limits for a class B digital device, pursuant to CE. These limits are designed to provide reasonable protection against harmful interferences in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: reorient or relocate the receiving antenna, increase the separation between the equipment and the receiver, connect the equipment into an outlet on a circuit different from that to which the receiver is connected, or consult the dealer or an experienced radio/TV technician for help.

2. POWER CONNECTIONS

Plug the power supply into an A.C. outlet. With the red dot on the connector facing the front of the unit, insert the Bio-Med Devices' plug-in power supply output connector into the mating connector on the left side of the ventilator. Attach a 50 psi source to the inlet on the right side. The use of an external filter/water trap is highly recommended. The air source may be a compressor or wall or tank compressed air source. All gas supplies should be clean, dry medical grade gas supplied unrestricted at 31 to 75 psi (214 – 517 kPa). If an air/oxygen blender is used, then 45 – 75 PSI (310 – 517 kPa) should be supplied to the blender.

CAUTION: When using an AC power source, only the power supply provided with the Crossvent is approved for use with this ventilator. Any other power supply may cause damage and/or unreliable operation.

CAUTION: Any more comprehensive DC power supply than that which is supplied must be short circuit protected and must comply with all of the specifications and standards as listed in Section III, Part B.

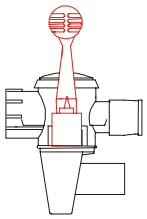
B- PATIENT CIRCUIT CONNECTIONS

WARNING: A patient filter should always be used in the patient breathing circuit to prevent cross contamination

WARNING: Do not re-use disposable breathing circuits.

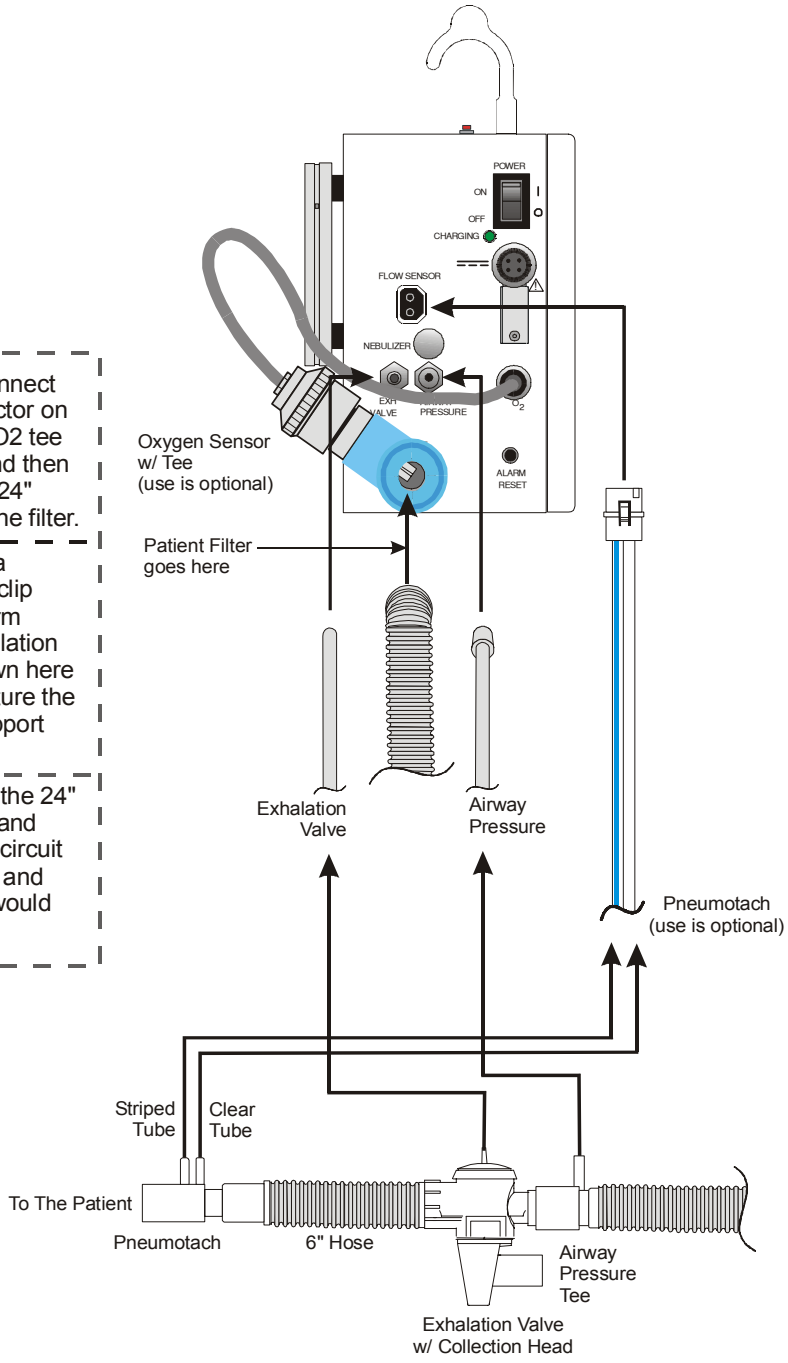
NOTES

When using a patient filter, connect it directly to the patient connector on the side of the Crossvent (or O2 tee if the sensor is being used) and then connect the patient circuit (or 24" hose if using a humidifier) to the filter.



For use with a support arm, clip the holding arm onto the exhalation valve as shown here and then capture the ball in the support arm.

When using a humidifier, use the 24" hose between the Crossvent and humidifier. Then connect the circuit to the output of the humidifier and make all the connections as would normally be made.



Adult circuit, catalog #80011, shown

FIG. 8- CIRCUIT SETUP

C- OPERATING INSTRUCTIONS

The following describes the procedure for setting up and operating the CROSSVENT-3+ Ventilator. It is assumed that the operator is thoroughly familiar with the Specifications, Theory of Operation, Tests and Calibration procedures as outlined in this manual. It is also assumed that the ventilator is already fully assembled, has been tested and calibrated and is connected to a test lung.

WARNINGS:

ONLY QUALIFIED MEDICAL PERSONNEL SHOULD OPERATE THE VENTILATOR.

WHENEVER THE CROSSVENT IS CONNECTED TO A PATIENT, A SKILLED OPERATOR SHOULD BE PRESENT AT ALL TIMES AT THE VENTILATOR OR WITHIN HEARING RANGE OF THE VENTILATOR'S ALARM SYSTEM.

DO NOT ATTEMPT TO VENTILATE A PATIENT UNTIL THOROUGHLY FAMILIAR WITH ALL OF THE OPERATING INSTRUCTIONS.

THE OPERATING INSTRUCTIONS ARE NOT INTENDED AS RECOMMENDED CLINICAL PROTOCOLS.

ALWAYS TEST THE VENTILATOR PRIOR TO EACH USE. AFTER SET UP, VENTILATE A TEST LUNG TO VERIFY PROPER OPERATION PRIOR TO CONNECTING THE VENTILATOR TO A PATIENT.

IF A MALFUNCTION SHOULD OCCUR, THE UNIT SHOULD BE REMOVED FROM USE AND REPAIRED PRIOR TO USING IT AGAIN ON PATIENTS.

WHENEVER AN ALARM CONDITION EXISTS IT SHOULD BE RECTIFIED IMMEDIATELY. NEVER ALLOW VENTILATION WITH AN ALARM CONDITION FOR AN EXTENDED LENGTH OF TIME.

NOTE: Since it is not possible to damage this CROSSVENT Ventilator by normal use of its keys and control knobs, the user is encouraged to experiment with the ventilator settings while the unit is not connected to a patient.

1- PRELIMINARY STEPS

Plug the power supply into an external electrical outlet and plug the power supply output connector into the jack of the ventilator.

Connect a patient circuit to the ventilator. Connect a test lung (BMD #1020 or #1022) to the proximal airway connector.

Connect a 50 psi gas supply source to the input connector.

2- DETAILED OPERATING INSTRUCTIONS

Turn the ON/OFF switch to the ON position. Following the "Bio-Med Devices" splash screen, the unit comes on in the Main menu in the same mode it was in when last turned off.

Press the ALARM QUIET key to increase the temporary audible alarm silence period from 60 sec. to 120 sec. if desired. It may be used as many times as necessary to cancel the audible alarm until the alarm limits are set. The EXTERNL or BATTERY indicator will come on depending on the condition of the power supply. If it is flashing "BATT", press this key to acknowledge battery mode. The ventilator will cycle at the rate set on the rate key and the inspiratory source CONTROL indicator will come on during each inspiration. If the ventilator auto-cycles, indicated by ASSIST or SPONT in the Inspiratory Source Key, the inspiratory effort should be increased using the Pressure Trigger key.

Select desired mode, e.g., SIMV.

The CROSSVENT-3+ primary function keys and control knobs should be set to the desired initial values, for example:

CONTROL	METHOD	SETTING
RATE	ARROWS	20 BPM
TIDAL VOLUME or	ARROWS	700 ml
INSP, if displayed	ARROWS	1 sec.
FLOW	KNOB	30 LPM
MAX PRESSURE (PIP)	KNOB	High "↷"
PEEP/CPAP	KNOB	Zero "↷"
PRESSURE TRIGGER	ARROWS	1 cmH_2O

NOTE: Highlighted field indicates that a parameter has been selected and may be adjusted using the arrow keys.

Set the alarms as desired in the ALARM1 and ALARM2 menus.

Verify proper operation.

Connect the ventilator to the patient.

Adjust PRESSURE TRIGGER and/or other controls for the particular patient. Observe operating parameters and make fine adjustments.

Press the Alarm1/Alarm2 key until the desired alarm menu is displayed. Select the desired alarm parameter you want to set, e.g., the HIGH PEAK PRESSURE key. This will change color. Use the arrow keys to select the desired value. This sequence of keys, i.e., alarm parameter limit and then arrow keys must be used when entering all limits. Once the limit has been entered into memory, it may be changed at any time by repeating the sequence.

WARNING: It is imperative to verify that clinically appropriate alarm limits are fully operational following connection of the ventilator to a patient.
WARNING: It is important to note that once a sensor has been turned off, the alarms for that sensor are inoperative.
NOTE: If it is desired to deactivate an optional alarm, select it and scroll the lower limit down to OFF. It is now inoperative. The function may be reactivated at any time by pressing it and scrolling the low limit up. It will now be reactivated. This allows the ventilator to be used without this particular alarm. When a sensor alarm is off, that sensor may be disconnected while the ventilator is in use, without causing an alarm.

3- SUMMARY OF OPERATING INSTRUCTIONS

Turn on.

Select mode.

Set primary functions in MAIN Menu.

Verify proper operation.

Connect to patient.

Make patient appropriate adjustments to settings.

Adjust alarm limits if desired.
***IMPORTANT** NOTE: Flashing I, E or I/E Ratio display indicates a timing limit violation and can be permanently silenced only by adjusting the settings to bring them into permissible ranges.*

V. SETUP MENU AND TROUBLESHOOTING

A- SETUP MENU

This menu allows the user to set preferences and perform test and calibration procedures relative to patient use. To access this menu, turn the ON/OFF switch to ON and press the SETUP key in the lower right corner of the display. The SETUP key is only available immediately after powering on the unit and is disabled as soon as any other key except ALARM QUIET or BATTERY is pressed or if no key is pressed within 30 seconds of power-up. The SETUP menu will be displayed and the alarm LED will light. From this menu, the CALIBRATION menu can be accessed by pressing the CAL MENU key or you can exit back to the MAIN menu by pressing the MAIN MENU key.

1- OXYGEN SENSOR CALIBRATION

This function is used to calibrate the Oxygen sensor cell. Due to the fact that O_2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed once a month in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

To calibrate:

1. With the O_2 Sensor cable plugged into the side of the CROSSVENT and the sensor out of the breathing circuit and open to atmosphere, press the OXYGEN key.
2. If the sensor has been exposed to a higher level of oxygen than just air in the last 5 minutes or so, then wait 3-4 minutes for the sensor to acclimate and then press the 21% key. Otherwise, you may press the key immediately. When the 21% is calibrated, it will return to the OXYGEN menu and the 21% will be green. If it is red, the calibration failed. Either replace the sensor and/or confirm no elevated level of oxygen is present.
3. Place the oxygen sensor tee onto the patient connector on the Crossvent and connect a breathing circuit with a test lung to the tee.
4. With the O_2 sensor cable still plugged into the ventilator, install the O_2 sensor into the tee.
5. Apply 100% oxygen to the ventilator input and set 20 cmH_2O of PEEP and 5 LPM flow.
6. Wait 3-4 minutes and then push the 100% key. When the 100% is calibrated, it will return to the OXYGEN menu and the 100% key will be green. If it is red, the calibration failed. Either replace the sensor and/or confirm the oxygen supply concentration is stable.
   NOTE: It is important to use the correct reference gases (100 and 21%) when performing this calibration. A worn out sensor will not calibrate accurately.

2- LEAK TEST

This test may be used to confirm the integrity of the patient circuit and its connections. To perform, proceed as follows:

1. Set the Max Pressure to its maximum setting.
2. Connect the patient circuit with a test lung to the Crossvent.
3. Set the flow control to 10 LPM.
4. Press enter. The Crossvent will pressurize the system and indicate "TESTING", followed by either "PASSED" or "FAILED" depending on the results. If it fails the test, check the patient circuit and all connections for leaks and retest.

3- TV/INSP PREFERENCE

Allows the user to choose between setting Inspiratory Time or Tidal Volume in the menus. Press INSP TIME and then exit the SETUP menu. INSP (inspiratory) will be displayed below the RATE key in the MAIN menu, thereby allowing the user to set an inspiratory time directly. If the user would prefer to set a Tidal Volume directly rather than an inspiratory time, then press TIDAL VOLUME in the SETUP menu and exit. Whichever is chosen will remain in effect until it is changed in this menu.

4- LANGUAGES

Allows for the menus to be displayed in a different language.

5- VER (Version)

Indicates the software version installed.

6- SN (Serial Number)

Indicates the serial number of this unit.

B- CALIBRATION MENU (CAL)

This menu is to be used only by someone skilled in the service and repair of the CROSSVENT Ventilator. Refer to the MAINTENANCE & SERVICE SECTION of this manual under Setup & Calibration Menu Overview for explanations of functions contained in this menu.

WARNING: Only qualified, trained, service technicians should attempt repairs and service when needed. Serious personal injury and/or equipment damage can result if unqualified personnel perform repairs.

C- OPERATIONAL TROUBLESHOOTING

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Fails to respond to touch selection of a key	1. Keys locked 2. Defective touchscreen key	1. Press LOCK key twice to unlock 2. Submit for service
Parameter value seems inappropriate	Wrong parameter selected	Select correct parameter
Unit fails to turn on when "ON/OFF" switch is set to on.	1. Battery low and plug-in power supply not connected. 2. No power at outlet and battery low.	1. Plug in charger to active outlet and charge battery 2. Plug into active outlet and charge battery
Internal regulator output pressure varies	Low pressure/flow from gas source; fault in gas supply	Increase gas volume/pressure
Low internal pressure regulator output	1. Output pressure not set; insufficient gas supply 2. Dirty or clogged filter	1. Set output pressure; check gas 2. Service needed
Incorrect peak pressure and PEEP/CPAP reading	1. Pressure transducer disconnected or malfunction 2. Pressure transducer is out of calibration	1. Service needed 2. Service needed
Uncontrolled auto-cycle; remains in inspiratory mode	1. Pressure Trigger setting is too sensitive 2. Pressure transducer malfunction	1. Increase Pressure Trigger setting 2. Service needed
System pressure reads zero	1.Peak pressure limit control is fully off 2. Tube disconnected between patient and ventilator	1. Adjust the maximum pressure limit control 2. Connect tube
Peak pressure high limit alarm activates	1. Accumulation of secretion 2. Change in compliance; blockage in airway or tubing 3. Patient tries to breath independently 4. Endotracheal tube has slipped down into a bronchus 5. Change in patient positioning 6. Pneumothorax 7. Sigh	1. Examine patient 2. Remove the blockage or replace the airway/tube 3. Re-evaluate patient status and vent settings 4. Correct the tube position 5. Re-evaluate patient and vent settings 6. Treat patient 7. Set the high alarm limit higher
Peak Pressure Low limit alarm activates	1. Disconnected patient circuit 2. Endotracheal tube has slipped down into a bronchus 3. Water in patient circuit 4. Decrease in lung compliance	1. Reconnect patient circuit 2. Reposition endotracheal tube 3. Empty water from patient circuit 4. Re-evaluate patient

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
Ventilator does not start	1. Power cable not connected and battery discharged 2. Low battery and no power in electrical outlet 3. Blown fuse in plug-in power supply 4. ON/OFF switch in the OFF position	1. Connect power cable; charge or replace battery 2. Change outlet; charge or replace battery 3. Replace power supply 4. Switch to ON
CROSSVENT fails to operate on battery	1. Low battery 2. Missing battery 3. Defective battery	1. Charge battery 2. Insert and attach battery 3. Replace battery
Battery fails to charge properly	1. Plug-in power supply not connected 2. No voltage at outlet 3. Defective battery 4. Defective charger	1. Connect plug-in power supply 2. Connect to an active outlet 3. Replace battery 4. Replace charger
LOW BATTERY indicator on	Battery discharged	AC power must be restored and battery charged
No exhaled tidal volume reading	1. Pneumotach out of circuit 2. Problem with flow channel or differential	1. Reinstall the pneumotach 2. Service needed
Incorrect tidal volume reading	1. Pressure limited 2. Incorrect flow calibration 3. Blocked or kinked pneumotach tubes 4. Leak in patient circuit or endotracheal 5. Inspiratory terminated by Peak Pressure high alarm limit	1. Adjust pressure limit 2. Submit for service 3. Check pneumotach tubes and correct blockage 4. Check and correct the patient circuit and endotracheal tube for leaks 5. Adjust Peak Pressure high alarm limit
Incorrect O_2 reading	1. O_2 sensor not connected 2. Incorrect calibration procedure 3. Faulty sensor cell	1. Connect sensor 2. Review calibration procedure and recalibrate 3. Replace cell
No O_2 readings	O_2 sensor turned off	Turn O_2 sensor on
Low Gas Supply flashing	Gas supply to ventilator is less than 31 PSI (214 kPa)	Connect a gas supply that can provide 31 to 75 psi (214 – 517 kPa) pressure at 132 lpm

VII. CLEANING, STERILIZATION AND PACKING

A- CLEANING AND STERILIZATION

The CROSSVENT Ventilator should be thoroughly cleaned and inspected following each patient use. The entire exterior of the unit should be cleaned with a suitable cleaning agent. During cleaning, power should be turned off and the plug-in power supply should be disconnected. Care should be taken not to allow cleaning agents to enter the unit as this could cause damage and subsequent malfunction.

> **CAUTION:** UNDER NO CIRCUMSTANCES SHOULD THE CROSSVENT UNIT BE GAS STERILIZED, STEAM AUTOCLAVED OR SUBMERGED IN LIQUID. THE COMPONENTS OF THE UNIT ARE INCOMPATIBLE WITH THESE STERILIZATION METHODS AND SEVERE DAMAGE CAN RESULT.

1- VENTILATOR- The entire unit, with the exception of the LCD touchscreen can be cleaned using an appropriate bactericidal or germicidal agent. Care should be used not to allow foreign material, e.g., cleaning agent, pieces of gauze, etc., to enter the unit. Particular care should be taken when cleaning near the connectors and vent screens.

2- LCD TOUCHSCREEN KEYPAD The touchscreen of the CROSSVENT is made of transparent plastic and may be damaged by chemical solvents and abrasive cleaners. Use only isopropyl alcohol when cleaning this area. Great care should be taken not to touch it with sharp objects, since it may be punctured, which could damage the keys.

3- PATIENT CIRCUIT- The complete patient circuit supplied with the CROSSVENT is disposable and intended for single use.

4- REUSABLE CIRCUIT- The optional Bio-Med Devices re-usable patient circuit may be gas or chemically sterilized as follows:

- Pasteurization at 150° to 170°F (65.6° to 76.6°C) for a minimum of 30 minutes.
- Ethylene Oxide (ETO) cold cycle not to exceed 130° F (54.4° C) with adequate aeration time.

5- OXYGEN TEE- The supplied blue oxygen tee may be sterilized with EtO (12%-88% or 100%) gas. Do not exceed 100°F. Aerate for at least 8 hours at 120°F.

B- PACKING FOR SHIPMENT

In the event the CROSSVENT must be returned to the factory, it is very important to pack the unit properly. The following is the correct packing procedure to insure safe transport:

Packing Materials Required:
- Double Wall Carton
- Suitable Shock Absorber - Foam or Air Bubble Wrap
- Poly Bag

For the safety of all concerned, please thoroughly clean and disinfect the unit prior to packing. If the unit is being returned for service, please include all information relative to its need for service as well as the name and phone number of the person we may contact regarding return.

If the unit you are returning is one that you received for evaluation, then all the accessories that came with the unit must also be returned as outlined here.

Procedure:

1. Cover CROSSVENT with the poly bag and secure with twist tie or tape.

2. Wrap the CROSSVENT in the foam or bubble wrap, with at least 2 inches of material on all sides, and place it into the carton.

3. Wrap oxygen sensor and any other adapters with bubble wrap (if returned).

4. Thoroughly wrap the power supply and power cord with bubble wrap and place it into the carton, making certain that it cannot damage the CROSSVENT while in transit.

5. Place the gas supply hose, if returned, between the rear of the CROSSVENT and the carton wall.

6. Place the patient circuits and instruction manual in an orderly fashion into the remaining space (if returned).

7. Fill the carton on all sides with packing material to prevent the unit from shifting during transit.

8. Close the carton with tape, noting serial number on the outside of the carton.

9. Ship to:

BIO-MED DEVICES, INC.
61 Soundview Road
Guilford, CT 06437 USA

MAINTENANCE & SERVICE SECTION

VIII. THEORY OF OPERATIONS

The CROSSVENT-3+ is a time cycled, volume or pressure limited ventilator. Its basic principle of operation is extremely simple. Supply gas, either air, oxygen, or a blended mixture, is connected to the CROSSVENT-3+ inlet fitting.

NOTE: For blended gas, the Bio-Med Devices blender should be used.

WARNING: In rare instances, when using the Crossvent with an air/oxygen blender, there may be a reduction in the delivered flow at the higher flow settings. This reduction may occur when the blender is set below 30% or above 90% O_2 and the Crossvent is set to flows above 80 lpm. Lower supply pressures to the blender will tend to decrease the flow further so be sure these supply pressures are maintained at 45- 75 PSI (310-517 kPa). If the Crossvent has the exhaled tidal volume monitoring feature, it is recommended this be used to ensure proper tidal volumes are being delivered. If it does not have this feature, then an external spirometer is recommended.

Gas flows first to an internal pressure regulator that provides output gas regulated to approximately 20 psi. This is used both for patient gas and to drive the pneumatic signals.

From the regulator the gas flows to a normally closed, 2-way, pilot valve operated by a miniature solenoid valve (valve A). The gas exits the pilot valve and goes to an electronically encoded flow valve. The encoding is accomplished via a precision potentiometer. Since the upstream (supply) pressure is constant and much greater than the downstream (patient) pressure, changes in downstream pressure may be neglected. Therefore, since the supply pressure is accurately regulated, the flow rate becomes a function solely of the flow valve setting. The length of time that gas flows is the inspiratory time. The volume of gas that flows during the on-time is the Tidal Volume and is equal to the on-time (inspiratory time) multiplied by the flow rate.

Upon exiting the flow valve, the gas then passes through the Diaphragm Actuated Relief Valve (D.A.R.V.) manifold. This manifold contains a fixed pressure relief valve to limit the maximum pressure as well as a variable relief valve that is controlled by the Max Pressure Knob. The gas then passes by the Vacuum Relief Valve, which allows the patient to draw in ambient air if the entire system becomes inoperative. Finally, the gas goes into the patient circuit through the patient connector.

During the period of time when valve A is open and gas flows, solenoid valve B is actuated, allowing gas from the Maximum Pressure valve to pressurize the diaphragm of the exhalation valve. This assures that all gas will flow to the patient. At the end of inspiration, valve A closes and gas flow ceases. Simultaneously, valve B is de-energized, connecting the PEEP valve signal to the exhalation valve diaphragm. This allows the patient to exhale to atmosphere and the pressure in the patient circuit to fall to PEEP or atmospheric pressure.

A low flow flush system is provided to prevent humidity from traveling back up the pneumotach sensing lines (if used) and damaging the pressure transducer. This is accomplished with two solenoid valves, D1 & D3. A third solenoid valve, D2, is used to zero the pressure transducer to compensate for drift. During inspiratory, these solenoids actuate. A very low flow is passed through solenoids D1 & D3 and out the pneumotach tubes. At the same time, the transducer ports are shunted through solenoid D2. This zeros the transducer by equalizing the pressure across it. During expiratory, these solenoids are de-energized and the pressure differential from the pneumotach is then passed through D1 and D3 to the transducer.

A- SYSTEM COMPONENTS

SUPPLY GAS INLET FILTER

The supply gas passes through an inlet filter that is located inside the supply gas fitting on the right side of the ventilator. This filter should be changed periodically as required. It filters particles down to 40 microns. If equipped with entrainment, there is a second filter in the venturi assembly at the inlet in the rear of the unit.

NOTE: It is recommended that an external filter/water trap be used on the supply gas at all times in order to provide greater protection to the internal components of the Crossvent.

SUPPLY PRESSURE SENSING SWITCH

A pressure sensitive switch is installed on the gas supply side of the internal pressure regulator. Should the gas supply pressure to the ventilator drop to a predetermined level, an audible and as well as visual alarm will occur.

AIRWAY PRESSURE TRANSDUCER

This connects to the proximal airway tube on the circuit through the fitting on the side of the unit. The pressure transducer converts the pressure signal into an electrical signal. This electrical signal, which represents the pressure waveform is then used by the CROSSVENT's microprocessors to accomplish a multitude of tasks. It is used to sense a pressure drop in the patient breathing circuit created by an inspiratory effort and then provide a trigger signal to initiate inspiration. The transducer output also establishes the levels for the all of the pressure related alarms.

DIFFERENTIAL PRESSURE TRANSDUCER

This component is only present if the unit has the optional Exhaled Tidal Volume monitoring feature installed. It is utilized to measure the pressure drop across an orifice in a pneumotachograph. The pneumotach (flow sensor) is placed at the proximal airway. As exhaled gas passes through the orifice, it creates a pressure drop from one side of the orifice to the other. This highly sensitive differential pressure transducer measures this small pressure difference. The signal from the transducer is then converted by the microprocessors into a measurement of exhaled tidal volume and minute volume.

MAXIMUM PRESSURE RELIEF VALVE

This valve vents gas to atmosphere whenever the pressure in the breathing circuit exceeds the preset level of 120 cmH_2O.

DIAPHRAGM ACTUATED RELIEF VALVE (D.A.R.V.)

This is controlled by the output signal from the Maximum Pressure needle valve (front panel), which is also applied to the exhalation valve. It sets the relief pressure at approximately the same level as the exhalation valve.

NEGATIVE PRESSURE RELIEF VALVE

This allows gas to enter the breathing circuit whenever a negative pressure greater than approximately 4-5 cmH_2O is generated. This acts as a failsafe mechanism and in the event of a total system power failure allows the patient to inhale ambient air.

WARNING: Breathing through this valve requires a greatly increased work of breathing and only air is provided. A situation in which the patient is breathing through this valve should be rectified immediately in order to prevent possible adverse affects to the patient.

WARNING: Should the use of the negative pressure relief valve become necessary, the operation of the Crossvent in a contaminated environment can be hazardous.

B- ASSIST CONTROL MODE

In this mode the CROSSVENT-3+ will function either as an assist or controller. If the patient is inspiring, the ventilator will sense the negative pressure created by the inspiratory effort and this will initiate an assisted inspiration. If the patient fails to breathe, the ventilator will continue to give controlled breaths at the backup rate as set by the main RATE setting.

Inspiration may be initiated by either a patient inspiratory effort or, in the absence of that, the backup setting. At the start of inspiration, gas flows to the patient at the flow rate established by the FLOW control, for the duration of the inspiratory time. Simultaneously, the exhalation valve is pressurized to the Maximum Pressure level. The maximum pressure attainable is established by the MAXIMUM PRESSURE control on the front of the ventilator. At the end of the inspiratory time, the patient gas flow is terminated and zero or PEEP pressure is applied to the exhalation valve.

The SIGH function can only be used in the Assist Control and SIMV modes. During a SIGH breath, the patient gas and Maximum Pressure remain on long enough to deliver the SIGH volume at the preset normal flow rate. This is equivalent to 1.5 times the volume set while the I/E ratio of a sigh breath is maintained at the same I/E ratio of a normal breath as set with the three primary controls: RATE, TIDAL VOLUME and FLOW.

C- SIMV (Synchronized Intermittent Mandatory Ventilation) MODE

In the SIMV mode, the CROSSVENT-3+ delivers two main types of breaths: ASSISTED and SPONTANEOUS. Both are initiated by the patient's inspiratory effort, which is sensed by the ventilator. The assisted breaths are the same as assisted breaths in the Assist Control mode. The rate of administration of assisted breaths is set using the SIMV RATE key and entering the desired value.

In between the assisted breaths, patient inspiratory efforts initiate spontaneous breaths. When the ventilator detects an effort to breathe, it initiates inspiration and delivers gas to the patient at a rate determined by the FLOW control and for a period of time equal to the inspiratory time of a normal assisted breath.

The difference between a spontaneous and assisted breath is that during a spontaneous breath, Maximum Pressure is not applied, only the PEEP pressure signal is applied to the exhalation valve, thus delivering gas to the patient at zero or PEEP pressure, if PEEP is on.

The full tidal volume is made available at the proximal airway. Whatever gas is not inspired by the patient is vented to atmosphere. At the end of the inspiratory time, should the patient desire a greater tidal volume than that which is set, he need only continue to inhale. As long as pressure below baseline (zero or PEEP) is detected, the ventilator will continue to deliver boluses of gas as determined by the TV setting. The patient is free to trigger as many spontaneous breaths as needed between assisted breaths. At the end of the time interval established by the SIMV RATE control, the ventilator administers an assisted breath, synchronized to the patient's breathing effort.

Pressure Support: When pressure support is turned on, the patient circuit pressure is allowed to increase above baseline (zero or PEEP) by the number of cmH_2O as set by PRESSURE SUPPORT. This occurs only during spontaneous breaths. When the airway pressure reaches the pressure support level, the baseline pressure is restored, allowing the exhalation valve to open, but the patient gas continues to flow for the duration of a normal assisted breath as set by the RATE and TIDAL VOLUME controls.

> **WARNINGS: It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the SIMV mode. Also, under certain conditions in SIMV with PEEP, even though the low peak pressure alarm is set correctly for assisted breaths, there may be no low peak pressure alarm following a patient disconnect until the next assisted breath. This period may be up to 2 minutes. As an added precaution, set the low PEEP/CPAP and low exhaled tidal volume (if installed) alarms so that they are operative.**

D- CPAP (Continuous Positive Airway Pressure)

In the CPAP mode, the breaths are delivered in exactly the same manner as a spontaneous breath in the SIMV mode. Each breath is triggered by the patient's inspiratory effort. Gas flows to the patient for a period of time equal to the inspiratory time of a normal assisted breath (established with the Tidal Volume and Flow controls). The flow rate during a CPAP breath is set with the Flow control. During CPAP breaths, Maximum Pressure is inactive and the gas is delivered at zero or CPAP pressure. The full volume is made available at the proximal airway, with additional boluses available with continued effort until the patient is satisfied. Whatever gas is not inspired by the patient is vented to atmosphere.

Pressure Support: See SIMV above.

WARNING: It is extremely important that the Pressure Trigger control be carefully adjusted to assure proper operation in the CPAP mode.

WARNING: Under certain conditions in CPAP, in particular with high flows and low CPAP pressures, if the low peak pressure alarm is set so that no false alarms occur, this alarm may be inoperative if a disconnect occurs. It is therefore extremely important to have the low PEEP/CPAP and low exhaled tidal volume (if installed) alarms set correctly.

E- BACKUP MODALITY

When in SIMV mode, the SIMV Rate is also the backup rate. When in CPAP mode, the backup rate is set with the Backup Rate key. In the event of apnea, the ventilator will deliver control breaths at this rate.

WARNING: It is important to always set a correct SIMV or BACKUP RATE, TIDAL VOLUME and FLOW to insure proper ventilation in case the patient becomes apneic.

IX. MAINTENANCE AND SERVICE

WARNINGS:
Technical repairs should be performed by qualified personnel, trained either by BIO-MED DEVICES, INC or their authorized trainers. Bio-Med Devices, Inc. is not responsible for unauthorized repairs, or repairs made by unauthorized procedures.

The CROSSVENT should pass a full technical performance check after any repair procedure that requires the case to be opened.

All safety measures must be observed when servicing this device. In particular, the ventilator must be turned off and the power supply disconnected.

Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

A- SETUP & CALIBRATION MENU OVERVIEW

The following is an overview of the SETUP and CALIBRATION (CAL) menus. Some functions in these menus will be used in the performance checks that follow this overview and will be further explained there.

To activate the SETUP and CALIBRATION menus, turn the ON/OFF switch to ON and press the SETUP key on the main menu. This key is only present immediately after power-on. It is removed and replaced by the ARROW keys by pressing any key with the exception of the ALARM QUIET or BATTERY key. When pressing the SETUP key, the SETUP menu is displayed. It is possible to go to the CALIBRATION menu by pressing the CAL MENU key or to return to normal operation at any time by pressing the MAIN MENU key.

1- SETUP MENU OVERVIEW

OXYGEN SENSOR CALIBRATION (if sensor is used)
This function is used to calibrate the Oxygen sensor cell.

NOTE: It is important to use the correct reference gases (100 and 21%) when performing this calibration. A worn out sensor will not calibrate accurately.

NOTE: Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed once a month in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

LEAK TEST
Tests the integrity of the patient circuit and its connections.

INSP/TV
Allows the user to choose between Inspiratory Time and Tidal Volume as it is displayed in the menus. When INSP TIME is pressed and the SETUP menu is exited, INSP (inspiratory) will be displayed below the RATE key in the MAIN menu, thereby allowing the user to set an inspiratory time directly. If tidal volume would rather be set, then press TIDAL VOLUME in the SETUP menu and exit. Whichever is chosen will remain in effect until it is changed in this menu.

LANGUAGES
Allows for the menus to be displayed in a different language.

VER (VERSION)
Indicates the software version installed.

SN (SERIAL NUMBER)
Indicates the serial number of this unit.

2- CALIBRATION MENU OVERVIEW

WARNING: Improper changes made in the Calibration menu can be detrimental to the performance of the ventilator.

The CALIBRATION menu can be accessed only from the SETUP menu. The CAL Menu is designed to aid service personnel in the testing and calibration of the ventilator. A password is required for some

calibration procedures to prevent unauthorized or untrained personnel from gaining access to these procedures as changes made can affect the operation of the ventilator. It is possible to exit the CAL menu and return to normal operation at any time by pressing the MAIN MENU key. When returning to the MAIN menu from the SETUP or CAL menus, the ventilator may not cycle due to invalid settings caused by changes to those settings made during test or calibration procedures. When the MAIN MENU key is pressed, a reminder to reset parameters is displayed prior to returning to the Main Menu to help avoid this.

BATTERY

Password required- This function is used to acclimate the battery gas gauge to a new battery when it is installed. It should only be used with a discharged battery. Refer to the instructions for battery removal and replacement under Disassembly and Reassembly Instructions in this manual for further details.

WARNING: This function should only be used on a discharged battery (6 volts or less). Using it otherwise can adversely affect the accuracy of the gauge.

PRESSURE TRANSDUCER

Password required- This function is used to calibrate the pressure transducer for accurate display of airway pressure. Refer to the Pneumatic Calibration section later in this manual for detailed instructions.

FLOW CALIBRATION

Password required- This allows for the calibration of the flow that is set by the Flow Knob on the front of the Crossvent. Flows are set and the flow value displayed here is compared with the actual flow being delivered as measured by a test instrument. Refer to the Pneumatic Calibration section later in this manual for detailed instructions.

TOUCHSCREEN (CALIBRATION)

This function is used to calibrate the x and y coordinates for the touchscreen. This is only necessary when a new touchscreen is installed or this calibration is lost due to a failure in the memory of the Crossvent. To calibrate the touchscreen, press TOUCHSCREEN in the Calibration menu. There will be displayed four boxes in the corner of the display. Press the point where the corners of these boxes converge. When the software registers the location that is pressed, these boxes will be replaced by a second group of boxes in the opposite corner of the display. Press the center of these as before. When the second point of reference has been registered, the calibration is complete and "CALIBRATED" is displayed. The unit then returns to the Calibration menu.

Caution: Pressing anywhere other than the converging points of these boxes may improperly calibrate the touchscreen.

KEYS (TOUCHSCREEN TEST)

Displays the Key Test menu. It is used to determine that the touchscreen is operating properly. Starting near the upper left corner of the display, press several points as you move diagonally down across the display towards the CAL MENU key. The values for the x and y coordinates for each point pressed should increase. If not, there is a problem with the touchscreen and it should be recalibrated. If calibrating does not fix the problem, then it should be serviced. Press the CAL MENU key to end this test and return to the CAL Menu.

DISPLAY (LCD) TEST

Tests all the pixels in the display by illuminating 16 boxes containing the 16 colors used by the Crossvent as shown below. Press anywhere on the touchscreen to end the test and return to the Calibration menu.

BLACK	BLUE	GREEN	CYAN
RED	MAGNENTA	BROWN	LIGHT GRAY
GRAY	LIGHT BLUE	LIGHT GREEN	LIGHT CYAN
LIGHT RED	LIGHT MAGENTA	YELLOW	WHITE

VALVES

May be used to activate the internal solenoid valves independently for calibration and troubleshooting purposes. The key adjacent to the designated valve indicates its current state. Pressing this key will change its state from OFF to ON and vice versa.

VALVE A -	PILOT VALVE (PATIENT GAS)
VALVE B -	SIGNAL PRESSURE TO EXHALATION VALVE
VALVE D1* -	PNEUMOTACH FLUSH
VALVE D2 -	EQUALIZES PRESSURE TRANSDUCER
VALVE D3* -	PNEUMOTACH FLUSH

*Valve A must also be on to have flow.

HOURS

Indicates the total accumulated hours the ventilator has been powered on.

FACTORY SERVICED

Indicates when the manufacturer last serviced the unit.

B- PERFORMANCE CHECKS

WARNING: If the CROSSVENT fails any of the following performance checks, remove the unit from patient service and submit for maintenance.

1- SETUP MENU

Turn on the unit and press the SETUP key.

OXYGEN SENSOR CALIBRATION

NOTE: Due to the fact that O2 sensors sometimes change output over time once exposed to atmosphere, a calibration should be performed once a month in order to assure optimal accuracy. When the sensor is consumed and does not calibrate properly, it should be discarded and a new sensor installed and calibrated.

With the O_2 Sensor cable plugged into the side of the CROSSVENT and the sensor open to atmosphere (not in the circuit tee), press the OXYGEN key.
Wait 3-4 minutes and then press the 21% key. When the 21% is calibrated, it will return to the OXYGEN menu and the 21% key will be green.
Connect the oxygen sensor tee to the patient connector on the side of the Crossvent and to it connect a breathing circuit with a test lung.
With the O_2 sensor cable still plugged into the ventilator, install the O_2 sensor into the tee.
Apply 100% oxygen to the ventilator input and set 20 cmH_2O of PEEP and 5 LPM flow.
Wait 3-4 minutes and then push the 100% key. When the 100% is calibrated, it will return to the OXYGEN menu and the 100% key will be green.
You may now check the O_2% readings in the Alarm Menu using a calibrated O_2 blender or Test Setup.

LEAK TEST

(This tests the integrity of the patient circuit and its connections)
Connect the patient circuit along with a test lung to the Crossvent.
Set the Max Pressure to its maximum setting.
Set the flow control to 10 LPM. Press enter.
The Crossvent will pressurize the system and indicate "TESTING", followed by either "PASSED" or "FAILED" depending on the results. If it fails the test, check the patient circuit and all connections, and retest.

2- CALIBRATION (CAL) MENU

If in the SETUP Menu, press the CAL key, otherwise turn the unit off and back on and press SETUP and then the CAL menu key.

KEYS

Press KEYS. Press on the display in various locations. Each time it is pressed in a different location, the coordinates displayed should change. If any location pressed fails this test, submit for service. Push CAL MENU to return to the CAL Menu.

DISPLAY

Press the DISPLAY key. The display will illuminate allowing you to check for missing pixels. Some randomly missing pixels is considered acceptable.

FLOW VERIFICATION

NOTE: For greatest accuracy, verify flow using a 60% O2 gas supply, (100% O_2 with Entrainment on if installed) making certain that the pressure to the CROSSVENT inlet remains within specified pressure limits (31-75 psi; 303.6 – 517.4 kPa) at all flows.

Remove the exhalation valve from the patient hose. Turn the Max Pressure knob fully clockwise. Make certain that the proximal airway pressure line and the pneumotach (if so equipped) are connected. Connect the patient hose to a certified flow measurement instrument. In the Cal menu, select VALVES and turn on Valve "A".
With the supply pressure maintained as defined in the preceding *NOTE*, turn the Flow Knob to its maximum setting and verify the flow indicated by the test instrument is within 108 - 132 LPM.
After verifying the maximum flow, adjust the flow knob to various flow levels, some high and some low, and verify that the flow displayed in this menu is within ±10% of the actual flow as indicated by the test instrument.
If the Crossvent is equipped with entrainment, turn it on and repeat these steps, paying heed to the NOTE above.

FLUSH

(Valve D1, D3- if equipped with Exhaled Tidal Volume monitoring)

Using a length of tubing, connect the lower orifice of the Flow Sensor jack on the side of the Crossvent to a low flow test standard and turn on the Crossvent.
Press SETUP and then CAL MENU.
Activate VALVES.
Turn ON valves A, D1 and D3, and set a flow of 40 LPM.
Check for a flow of 40 - 60 ml/min coming from the orifice.
Move the tubing connection from the lower orifice to the upper orifice in the Flow Sensor jack.
Check for a flow of 40 - 60 ml/min coming from this orifice also.

POP OFF

Install a patient circuit with the end occluded (plugged, no test lung). Rather than connecting the airway pressure line to the Crossvent, however, connect this to a low pressure test instrument.
Turn on the CROSSVENT and press the SETUP/CAL MENU/VALVES keys. (If the Crossvent is already on and the Arrow keys are present, turn it off and back on to make the SETUP key available).
Set the Max Pressure Knob fully clockwise.
Set the flow to 20 lpm.
Turn on Valve A by pressing its corresponding ON/OFF key.
Occlude the exhaust opening of the exhalation valve on the circuit while observing the test instrument reading. It should indicate between 96 and 144 cmH_2O.
Increase the flow until it is at its maximum setting. The pressure should not exceed 144 cmH_2O.

3- MAIN MENU

BAR GRAPH ACCURACY

Disconnect the patient circuit.
Tee the airway pressure fitting on the side of the Crossvent to a low-pressure measurement instrument and a 10-25 ml syringe (or similar).
Turn on the CROSSVENT in the MAIN menu and set:

RATE to 20
TV ml to 500
FLOW to 15
In the ALARM 1 menu, set the PEAK PRESS Alarm high limit to its maximum setting
In the ALARM 2 menu, set the PEEP alarm high and low limits to their maximum settings.

As the unit cycles, slowly depress the plunger on the syringe. Stopping at various pressures along the bar graph, verify the readings on the bar graph are within ±10% of the readings on the test instrument.

PEEP PRESSURE SIGNAL

Connect the Exhalation Valve fitting on the side of the Crossvent to a low pressure test instrument.
With the PEEP Knob fully clockwise, the pressure reading should be 15-20 cmH_2O.

BATTERY ALARM

(This alerts the user they are in battery mode)

Turn on the CROSSVENT without external power.
BATTERY key will flash as well as the LED.
The audible alarm is silenced for 60 seconds when unit is initially powered on.
Press the BATTERY key to acknowledge battery mode and to cancel the Battery Alarm.
The BATTERY key will revert to its normal state with its bar graph indicating the percentage of battery charge left.

EXTERNAL POWER FAILURE ALARM

Connect the Bio-Med Devices Crossvent Power Supply to the power input on the side of the Crossvent. (This connector is keyed. Red dot to front of unit.).
With the CROSSVENT turned ON, EXTERNL will appear in the lower left of the display.
After 1 minute of operation, remove external power plug.
EXTERNL will change to BATTERY and flash. The LED will flash and the audible alarm will sound.
Press BATT to stop the alarm.
The BATTERY key will revert its normal state with its bar graph indicating the percentage of battery charge left.

POWER FAILURE ALARM

(Occurs when CROSSVENT looses power or is turned off)
With the CROSSVENT operating for a minimum of 1 minute, turn the CROSSVENT off with the On/Off Power Switch.
The LED will flash along with an audible alarm. Press the reset button the left side of the unit to silence the alarm.

SUPPLY PRESSURE ALARM

With the ventilator connected to a 50 psi gas source and powered on, lower the supply gas pressure to approximately 31 PSI. The ventilator should alarm.
Raise the pressure back to 50 psi. The alarm should cease.

ALARM QUIET

With the CROSSVENT cycling and Alarm Quiet inactive, cause the unit to alarm, i.e., remove the patient circuit. The audible alarm should sound along with a flashing LED.
Press the ALARM QUIET key and verify that the alarm silences for 60 sec.
Press the ALARM QUIET key twice and verify that the alarm silences for 120 sec.
Press it a third time to cancel.

BACKLIGHT

While operating on battery, press the middle of Pressure Bar Graph, hold until a second beep is heard (≈3 seconds) and verify that the BACKLIGHT turns off. Press anywhere on the display to turn back on.

LOCK

Press LOCK and verify that all functions except the MENU KEYS and ALARM QUIET are locked out.
Press LOCK once and then again within 5 seconds to unlock.

USE THESE SETTINGS FOR THE FOLLOWING TESTS UNLESS OTHERWISE INSTRUCTED:
Rate = 20 bpm; TV = 500 ml; Flow = 30 lpm

ASSIST CONTROL FUNCTIONS (SET TO Assist Control MODE)

RATE

Connect a patient circuit to a Rate Test Standard and cycle the Crossvent.
Set various RATE settings and verify that delivered rates are within 10% of the set rate.

TIDAL VOLUME

Connect the patient circuit to a Tidal Volume Test Standard.
Turn on the unit and set the Max Pressure knob fully CW.
Set the TV (see note) to 200 and Flow to 20 and verify delivered Tidal Volume is within 10%. Repeat for TV 500, Flow 30; TV 1000, Flow 60; TV 2000, Flow 80.

NOTE: If TV is not displayed under the RATE key, then go into SETUP, press TV/INSP and select Tidal Volume as the preferred parameter.

SIGH

Connect the patient circuit to a Tidal Volume Test Standard.
Activate SIGH and verify the tidal volume is increased to 1.5 times the set tidal volume for the SIGH breath.

ALARM MENUS

Exceed each limit, HIGH and LOW, in the menu and verify the ventilator alarms.

SIMV FUNCTIONS (SET TO SIMV MODE)

SIMV BACKUP RATE

Turn ON the Crossvent.
Connect the unit to a Rate Test Standard.
With the SIMV RATE set to 20 and without initiating a breath with effort, verify the unit delivers controlled breaths at the set rate.

PRESSURE SUPPORT

(MAIN MENU)
Set PRESSURE SUPPORT to 10 cmH_2O and initiate breaths using inspiratory effort. Verify that the high-pressure signal to the exhalation valve is terminated when the circuit pressure equals 10 cmH_2O above PEEP during spontaneous breaths only, and that the gas flow remains on for the duration of the set inspiratory time.

PRESSURE TRIGGER

(MAIN MENU)
Tee a calibrated low-pressure analog gauge into the airway pressure line of a patient circuit.
Set Pressure Trigger to -1.0 cmH_2O and verify the CROSSVENT triggers a breath when a pressure of -1 cmH_2O is applied to the circuit.
Repeat for -5 cmH_2O.

CPAP FUNCTIONS (SET TO CPAP MODE)

MANUAL

Press the MANUAL key and verify a pressurized breath is delivered and MAN is displayed in the lower left key during this breath.

C- RECOMMENDED TOOLS AND TEST EQUIPMENT

1- Special Tools and Test Equipment

Items available from BMD

Part Number	Description
1020	Test Lung
80011	Patient Circuit
2002K	O2 Blender

Items NOT available from BMD

Item	Description
Anti-Static Cable	Anti-Static mat ground cable ass'y.
Anti-Static Mat	Workbench cover
Anti-Static Strap	Wrist Strap
Digital Voltmeter	Multimeter
Syringe and tee	25 or 50 ml. with .170" barb tee
DC Power Supply	0- 30 VDC @ 2A min.
Pressure Standard	-30 to +140 cmH20 ±0.5 cmH_2O
Temperature Standard	80 to 110 degrees F; ±0.2 deg. F
Oxygen Analyzer	21 to 100 %; ±1%
Oscilloscope	100 MHz, Storage
Krytox® 240 AD	Grease

Common Tools

Item	Description
Allen Hex Drivers	Up to 5/32"
Diagonal Cutters	
Hemostat	4" or similar
Needle Nose Pliers	
Screw Driver	Assorted

D- PREVENTATIVE MAINTENANCE

1- RECOMMENDED MAINTENANCE SCHEDULE

Periodic preventive maintenance should be performed to insure continued proper operation of the CROSSVENT-3+ Ventilator. The frequency of preventative maintenance is determined by many factors, some of which are:

- Frequency & length of use
- Quality of the compressed gas source(s)
- Environmental conditions

TIMELINE

The following is a list of routine maintenance procedures and maintenance schedule.

Interval	Recommended Procedures
Prior to each use	Check battery condition
Periodic	Performance Check
Annual	Verify Calibration
Every 2 years	Major overhaul, cleaning and calibration Battery replacement* **Recommend return to factory for this service**
Every 6 years	Replace PC Board

***Replace only with batteries supplied by Bio-Med Devices, part # PRT4467. Do not substitute.**

Note: Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

GAS INLET FILTER

The filter element should be replaced during major overhauls or whenever it becomes clogged. The gas supply filter is in the supply inlet fitting (DISS O_2 Input) and is in every unit. If the unit has air entrainment, then there is an additional filter in the entrainment inlet located in the back of the unit. Both filters should be replaced at the same time.

BATTERY CHECK

The battery has an internal thermal fuse. This fuse will open if it gets hot due to excessive current flow or if the battery itself becomes too hot. It will recover when the cause is eliminated. If the fuse is suspect, check for voltage across the red and black wires coming from the battery. If the battery is hot and no voltage is present, allow it to cool and check again. If there is no voltage and it won't take a charge, but the charging circuit is good, replace the battery.

The battery should be checked before each use.

To check:

Turn on the Crossvent and remove the external power supply connector. The ventilator should continue to operate correctly. The Power Source key should display "BATT" and the audible alarm should sound. Pressing the Power Source key should permanently silence the audible alarm. Restoring the external power should cause the Power Source key to show "EXTERNL". If a battery operation alarm does not sound when AC power is lost or if the unit fails to operate on battery, the unit should be removed from service and tested.

One minute after turn-on observe the battery bar gauge. If the bar gauge originally showed 100% and now shows less than 75% charge remaining, put the CROSSVENT on charge. Recheck in 6 hrs. If the battery condition has not improved, remove the unit and power supply from service until the problem is identified and corrected.

2-PREVENTIVE MAINTENANCE PARTS KITS

Part Number	If your Crossvent has:	
	Flow Sensor	Entrainment
PRT3348	NO	NO
PRT3350	NO	YES
PRT3353	YES	NO
PRT3354	YES	YES

Included in the kits are the following parts: Filter(s), MAX/DARV Pressure Line, PEEP Pressure Line and Flush Line if it has the flow sensor. Additionally, it is recommended that the Battery be replaced every two years. If the small, clear tubing off the regulator shows any contamination or discoloration inside, then the Crossvent should be thoroughly inspected for contamination throughout all its pneumatic components and pathways. This may indicate a contaminated gas source and this should be investigated and rectified before placing the ventilator back in service. Minimally, in addition to the PM Kit, the Flow Valve, MAX Pressure Valve, and PEEP Pressure Valve should be replaced under these circumstances. A slightly cloudy look to the large clear tube from the regulator to the flow valve may be normal for this tubing material. The small, clear tubes should be clear, however.

For instructions on replacing these parts, refer to the Disassembly & Reassembly Section later in this manual.

E-SOFTWARE UPGRADES

RS-232 COMPUTER INTERFACE - A 6 pin, modular jack is provided as a convenient PC interface for software updates. It is located in the rear of the unit behind the rear panel.

On occasion, software upgrades may be released with further enhancements to the Crossvent. These are available through Bio-Med Devices or your dealer. It is a rather simple task to install new software into the Crossvent, but this should be done by qualified personnel as the rear panel of the ventilator must be removed to access the RS232 jack used to download the software.

When requesting new software, the serial number of the Crossvent is required. Each software download is defined for a specific Crossvent, identified by its serial number. Without the proper serial number, the software will not load.

When ordering software, use part #PRT4427C. Along with the software, a communication cable and adapter to connect it to a computer are included. This adapter is custom and may not be substituted. Keep this cable and adapter in a safe place for future use. If you have these, then often times any future software upgrades can be emailed.

F- PNEUMATIC CALIBRATION

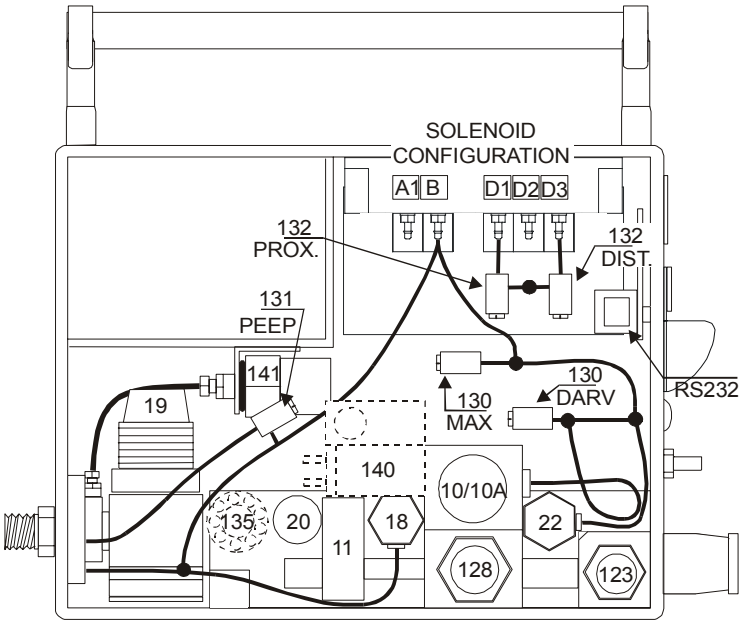


FIG. 10- PNEUMATIC CALIBRATION

10 DARV (Diaphragm Actuated Relief Valve)
11. Flow Valve
18. PEEP Valve
19. Logic Regulator/Pilot Valve
20. Potentiometer
22. Maximum Pressure Valve
123. Vacuum Relief Valve
128. Positive Pressure Relief Valve
130. DARV Variable Resistor
130. Max Pressure Variable Resistor
131. PEEP Variable Resistor
135. Entrainment Flow Valve (Optional)
132. Proximal Flush Variable Resistor
132. Distal Flush Variable Resistor
140. Entrainment Venturi (Optional)
141. Pressure Sensing Switch

The steps in these procedures are divided into two parts. The first part is "TO TEST". This describes the procedure used to test each specific component of the unit to determine its condition. The second part is "TO CALIBRATE". This part describes the calibration procedure of that component if it did not pass the preceding test.

IMPORTANT: The calibration steps need only be performed on those components that fail the "TO TEST" procedure. Generally, calibration is only required when parts are serviced or replaced so be sure to troubleshoot any failed test thoroughly prior to resorting to calibration.

> **CAUTION:** With the PC Board removed, great care should be taken to protect the board from stray voltages, static electricity, and any other environmental concerns that may damage the board. Always handle the board with care and be sure you and your work surface are properly grounded.

1. GAS SOURCE - 60% O2 / 100% O2

a. To ensure the most accurate calibration throughout all settings on the CROSSVENT, a blended gas source of 60% O2 should be used.
b. 100% O2 should be used when entrainment is on, if installed.

2. SUPPLY PRESSURE - 31 - 75 PSI (303.6 – 517.4 kPa)

a. The pressure at the supply input on the CROSSVENT (not at the supply source) must be maintained between 31 - 75 PSI (303.6 – 517.4 kPa) at all times.

3. PEEP VALVE ZERO - ≤20 ML/M

TO TEST:

a. Connect the exhalation valve port on the side of the CROSSVENT to a low flow test instrument.
b. Using hemostats or a similar tool, clamp off the blue PEEP tube between the small tee fitting and the white bleed manifold mounted to the side of the case. Also clamp off the orange tube between the PEEP Variable Resistor (131) and the bleed manifold.
c. Turn the PEEP Valve (18) shaft fully CCW until a flow ≤20 ML/M is obtained as observed on the test instrument (Slight resistance in the valve at this point is normal, however, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

d. Clamp off the blue PEEP tube between the small tee fitting and the white bleed manifold mounted to the side of the case. Also clamp off the orange tube between the PEEP Variable Resistor (131) and the bleed manifold.
e. Remove the shaft extender from the valve shaft by loosening the two setscrews. Turn the valve shaft until the specification stated above (3c) is met. Position the shaft extender on the PEEP Valve shaft with its stop pin against the left side of the stop. Tighten the setscrews in this position.
f. Remove hemostats.

4. MAXIMUM PRESSURE VALVE ZERO - ≤20 ML/M

TO TEST:

a. Connect the exhalation valve port on the side of the Crossvent to a low flow test instrument.
b. Using hemostats or similar tool, clip off the yellow tube coming off the side of the DARV. **CAUTION:** Failure to do this could result in damage to the ventilator in the steps that follow.
c. Using hemostats or a similar tool, clamp off the orange tube between the DARV Variable Resistor (130) and the white bleed manifold mounted to the side of the case. Also clamp off the orange tube between the MAX Pressure Variable Resistor (130) and the bleed manifold.
d. In the CAL menu, activate valves, and turn on valve B.
e. Turn the MAX Valve (22) shaft fully CCW until a flow ≤20 ML/M is obtained as observed on the test instrument. (Slight resistance in the valve at this point is normal, however, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)
f. Remove the clamps from the orange bleed tubes before removing the clamp from the yellow tube to the DARV.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

g. Remove the DARV orange test plug from the cross next to the DARV Variable Resistor (130) and connect this barb to a low flow test instrument.
h. Clamp off the orange tube between the DARV Variable Resistor and the white bleed manifold as well as the orange tube between the MAX Pressure Variable Resistor and the bleed manifold.

i. Remove the shaft extender from the valve shaft by loosening the two setscrews.
j. Turn the valve shaft until the specification stated above (4e) is met. Position the shaft extender on the MAX Valve shaft with its stop pin against the left side of the stop. Tighten the setscrews in this position.
k. Remove hemostats.

5. FLOW VALVE/POTENTIOMETER ZERO - ≤500 ML/M

WARNING: Any time the flow valve(s) are disturbed, the flow calibration in the CAL menu must be performed as explained in Steps 13 & 14.

CAUTION: The Flow Valve (11) is geared to the Potentiometer (20) and it is the rotational limits of the potentiometer that stops the valve from turning. Do not force.

TO TEST:

a. Connect the Patient Connector on the side of the CROSSVENT to a low flow test instrument using a single length of tubing.
b. Occlude the opening of the DARV or turn up MAX Pressure fully if it's calibrated.
c. In the CAL menu, activate valves, and turn on valve A.
d. Turn the Flow Knob fully CCW to the stop. Flow should be ≤500 ML/M as observed on the test instrument.
e. Entrainment Flow Valve (optional feature) - set up same as above (5a-c). Set the Entrainment Switch to ON. From the back of the unit, occlude the entrainment inlet in the venturi.
f. Turn the Flow Knob fully CCW to the stop. Flow should be ≤500 ml/M as observed on the test instrument.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

g. Remove the PC Board. (See the caution at beginning of the calibration procedures.)
h. Remove the gear from the Potentiometer by loosening the setscrews located in the teeth of the gear. There will be two setscrews per hole, one on top of the other. Remove the top one and then loosen the one underneath.
i. Carefully disconnect the clear tube from the PEEP Valve (18). Be sure the supply pressure is off at this point. Carefully remove the green tube where it is connected to the Pilot Valve at the bottom of the Regulator and connect the clear tube from the PEEP valve here. This will turn on the patient flow whenever the supply pressure is turned on, thus bypassing the software and solenoid.

If your unit has entrainment, continue with step j, otherwise go to step m.

j. **Zero the Entrainment Flow Valve** (optional feature) – On the entrainment venturi assembly, carefully remove the clear tube from the barb that is closest to the front of the Crossvent in the top row. Connect this tube to a low flow test instrument.
k. Turn on entrainment, turn on the supply gas, and turn the Entrainment Flow Valve shaft CW until ≤500 ml/M is obtained. Leave the valve in this position.

NOTE: The front of the valve gear should be flush with the end of the shaft and when the valve is properly zeroed, the setscrews should be on the bottom (5 & 7 o'clock position). If they are not, loosen them and reposition the gear so they are. The unit will have two screws per hole, one on top of the other. Remove the top setscrew and then loosen the bottom one in both holes. To tighten, tighten the shorter one inside the hole first, then install and tighten the second setscrew (approximately 1 inch-pound [.01 kg]). Do not over tighten the second one or the gear may distort causing it to bind when engaging the potentiometer gear.

l. Reconnect the clear tube to the entrainment barb.
m. **Zero the Flow Valve** - Connect the Patient Connector on the side of the CROSSVENT to a low flow test instrument using a single length of tubing.
n. Turn on the supply pressure, occlude the opening of the DARV, or turn up MAX Pressure fully if it's calibrated, and turn the Flow Valve shaft CW until the flow measured is ≤500 ml/M. DO NOT FORCE. (Slight resistance in the valve at this point is normal. However, do not force the valve. If abnormal resistance is felt prior to the valve closing to within this specification, it should be replaced.)

NOTE: See note in 5k regarding the position of the flow gear relative to the flow shaft .

o. **Reinstall the Potentiometer Gear**- While leaving the Flow Valve in the zero position, turn the Potentiometer shaft fully CCW until it stops. Place the Potentiometer gear onto the shaft so its setscrews are facing 180° opposite the screws on the flow shaft(s), i.e., at the top if the Flow Valve setscrews are at the bottom. (This helps prevent binding as the gears are turned.) Referring to Fig. 11, tighten the inner setscrews and replace and tighten the outer setscrews.
p. Test again and ensure that the Potentiometer hits its stop at the same time the Flow Valve reaches zero. DO NOT FORCE. Reconnect all tubing to their original state.
q. The flow calibration will have to be verified prior to putting the Crossvent back in service. See the flow calibration procedure later in this section.

r. When the preceding steps have been completed, the gear(s) should appear as above. The potentiometer gear should be positioned on the shaft so that its front face is forward of the flow gear(s) by half its thickness. This enables proper engagement throughout the full travel of the flow shaft(s). As they turn, the gears on the flow shaft(s) will move forward such that when they are at the end of their rotation and are in the fully open position, they will be beyond the potentiometer gear by half its thickness.

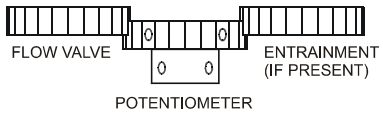


Fig. 11- Gears with Valves Closed

6. LOGIC REGULATOR - APPROX. 19/26 PSI (perform first - 5)

REMINDER: Supply should be 60% O2 (100% O2 with entrainment on, if installed).

TO TEST:

a. Connect the Patient Connector on the side of the CROSSVENT to a high flow test instrument using a single length of tubing.
b. Occlude the opening of the DARV or turn up MAX Pressure if it's calibrated.
c. In the CAL menu, activate valves, and turn on valve A.
d. Turn the Flow Valve fully CW. The maximum flow should be within 108 - 132 LPM (102 - 138 LPM with entrainment on, if installed).
e. If this test fails, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Remove the locking o-ring between the red locking ring and the Regulator Adjusting Knob and lift the ring towards the knob to unlock it.
g. Remove the orange test plug from the tee located on one of the four clear tubes just off the regulator and connect a high pressure gauge here.
h. Connect the Patient Connector on the side of the CROSSVENT to a high flow test instrument using a single length of tubing.
i. Occlude the opening of the DARV or turn up MAX Pressure if it's calibrated.
j. In the CAL menu, activate valves, and turn on valve A.
k. Turn the Flow Valve fully CW. (Entrainment off, if installed).
l. Turn the Regulator Adjusting Knob until the specification stated above (6d) is met. The pressure as indicated on the gauge (6g) should be approximately 19 PSI (26 PSI if the CROSSVENT has the entrainment option installed). This pressure will vary slightly from unit to unit and is dependent upon the pressure required to obtain the maximum flow, therefore no specific pressure is given. However, if the pressure required is significantly higher or lower than these values, then there may be a problem, i.e. restriction, leak, etc.
m. Remove the test gauge and replace the test plug. Snap the locking ring back down in place and replace the o-ring.

7. PEEP SIGNAL - 17 cmH_2O (perform first - 3, 5, 6)

TO TEST:

a. Connect the exhalation valve port on the side of the CROSSVENT to a low pressure test instrument.
b. Fully open the PEEP Valve.
c. Pressure should be 15 - 20 cmH_2O.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

d. Set up as in 7a-b.
e. Adjust the PEEP Variable Resistor (131) to obtain 7c.

8. MAXIMUM PRESSURE SIGNAL - 60 cmH_2O (perform first - 4, 5, 6)

TO TEST:

a. Connect the exhalation valve port on the side of the CROSSVENT to a low pressure test instrument.
b. In the CAL menu, activate valves and turn on valves A and B.
c. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument).
d. Fully open the MAX Pressure Valve.
e. Pressure should be 54 - 66 cmH_2O.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 8a - d.
g. Adjust the MAX Pressure Variable Resistor (130) to obtain 8e.

9. DARV SIGNAL - 65 cmH_2O (perform first - 5, 6)

TO TEST:

a. Remove the orange test plug from the cross next to the DARV Variable Resistor (130). Connect this barb to a low pressure test instrument.
b. Fully open the Max Pressure Valve.
c. In the CAL menu, activate valves and turn on valve A.
d. Set the flow to 40 LPM (if the flows are not calibrated, then set this using a test instrument)
e. Pressure should be 5 cmH_2O above MAX Pressure as measured in Step 8.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 9a - d.
g. Adjust DARV Variable Resistor to obtain 9e.

10. FLUSH - 50 ML/M (perform first - 5, 6)

(Units with exhale tidal volume monitoring installed only)

TO TEST:

a. Using a length of tubing, connect the lower orifice of the Flow Sensor jack on the side of the Crossvent to a low flow test standard and turn on the Crossvent.
b. Press SETUP and then CAL MENU. Activate VALVES.
c. Turn ON valves A, D1 and D3, and set a flow of 40 LPM (if the flows are not calibrated, then set this using a test instrument).
d. Check for a flow of 40- 60 ml/min coming from the orifice.
e. Move the tubing connection from the lower orifice to the upper orifice in the Flow Sensor jack and check for the same flow.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

f. Set up as in 11a - c.
g. Adjust the Distal Variable Resistor (132) to obtain 11d.
h. Adjust the Proximal Flush Variable Resistor (132) to obtain 11d.

11. POSITIVE RELIEF VALVE - 96 - 144 cmH_2O (perform first - 5, 6)

TO TEST:

a. Connect the Patient Connector on the side of the CROSSVENT to a low pressure test instrument using a single length of tubing.
b. Occlude the opening of the DARV.
c. In the CAL menu, activate valves, and turn on valve A.
d. Starting with the valve fully CCW, turn the Flow Knob fully CW while observing the test instrument. The pressure should be no less than 96 cmH_2O with $\geq$20 LPM and no greater than 144 cmH_2O with $\leq$120 LPM.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Set up the same as 10a - c.
f. Turn off valve A and remove the Positive Relief Valve (128).
g. From the underside of the valve, adjust the tension on the spring to obtain 12d by holding the spoked spring seat and turning the center poppet with a screwdriver. Turn CW if pressure is too high and CCW if too low.
h. Reinstall and test.

12. VACUUM RELIEF VALVE - - 4 cmH_2O (perform first - 5, 6)

TO TEST:

a. Connect the Patient Connector on the side of the CROSSVENT to a low flow test instrument using a single length of tubing. Into this tube, tee a low pressure vacuum test gauge.
b. Occlude the opening of the DARV.
c. Connect a controlled vacuum generating device to the output of the low flow test instrument so that air can be drawn through it.
d. Slowly increase the vacuum while observing the flow test instrument and the vacuum gauge. The Vacuum Relief Valve (123) should start to open between -3.5 and -4.5 cmH_2O and the flow test instrument should indicate this by showing some flow at this point.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Set up the same as in 11a - c.
f. Remove the Vacuum Relief Valve (123). While holding the poppet from turning with your finger, adjust the tension on the spring by turning the spoked spring seat. Turn it CW to increase and CCW to decrease pressure.

g. Reinstall and test.

13. FLOW (entrainment off) (perform first - 5, 6, 7, 8, 9)

NOTE: For greatest accuracy, verify flow using a 60% O2 gas supply making certain that the pressure to the CROSSVENT inlet remains within specified pressure limits (31-75 psi; 303.6 – 517.4 kPa) at all flows. This may require a supply pressure to the blender to be 70 PSI or greater when checking the higher flows.

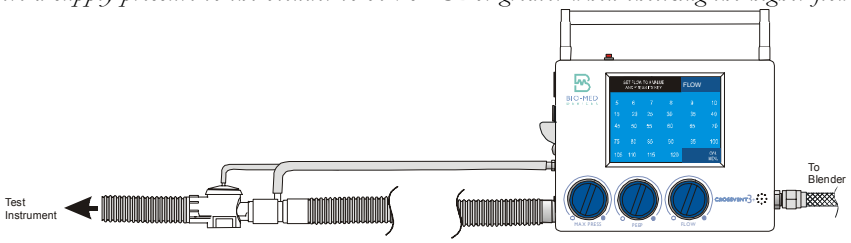


FIG. 12- FLOW TEST SETUP

TO TEST:

a. Connect a patient circuit to the Crossvent as illustrated.
b. Increase the supply pressure to the blender to 75 psi.
c. Turn Max Pressure and PEEP on fully, making certain that the airway pressure tube is connected.
d. Connect the patient hose to an external test instrument capable of measuring flow.
e. After turning ON the CROSSVENT, press the SETUP Key, then CAL MENU and then VALVES.
f. Turn on Valve A.
g. Adjust the flow knob and observe the flow as indicated on the test instrument. It should be within 10% of the displayed flow on the Crossvent where it indicates "FLOW".
h. If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

i. Press "FLOW" in the CAL menu.
j. Adjust the flow knob until the actual measured flow, as indicated on the test instrument, is equal to 5 lpm. Then compare this actual measured flow to the flow value indicated in the upper portion of the Crossvent display. If the flow as indicated by the Crossvent is within ±10% of the actual flow, in this case 4.5 – 5.5 lpm, proceed with the next flow point in the table. If it is not within the 10% limits, press the "5" key in the table corresponding to the actual flow. The displayed flow on the Crossvent should now display 5 lpm. The flow knob is now calibrated to the actual flow for that setting. Repeat for all other flow points.

14. FLOW (entrainment on) (perform first - 5, 6, 7, 8, 9)

NOTE: Verify flow using a 100% O2 gas supply making certain that the pressure to the CROSSVENT inlet remains within specified pressure limits (31-75 psi; 303.6 – 517.4 kPa) at all flows.

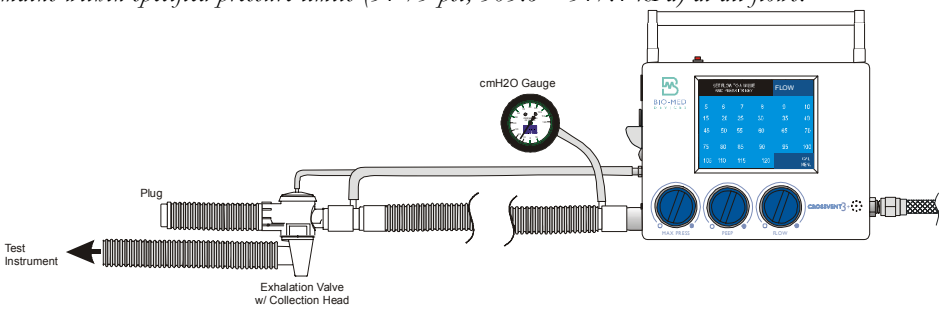


FIG. 13- ENTRAINMENT FLOW TEST SETUP

TO TEST:

a. Connect a patient circuit to the Crossvent as illustrated.
b. Turn on entrainment using the knob on the side of the ventilator.
c. Turn Max Pressure on fully, making certain that the airway pressure tube is connected.
d. Connect the patient hose from the exhaust of the exhalation valve to an external flow-measuring device.
e. In the CAL menu, press FLOW to access the Flow Test Menu.

f. Adjust the PEEP Knob until 15 cmH_2O is observed on the analog gauge. All flow readings should be taken with this backpressure. Readjust as necessary as each flow value is set. At the higher flows, this pressure may go above 15 cmH_2O and you may not be able to adjust it down. This is acceptable.

g. Adjust the flow knob and observe the flow as indicated on the test instrument. It should be within 10% of the displayed flow on the Crossvent where it indicates "FLOW". If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

h. Setup same as above.

i. Adjust the flow knob until the actual measured flow, as indicated on the test instrument, is equal to 5 lpm. Then compare this actual measured flow to the flow value indicated in the upper portion of the Crossvent display. If the flow as indicated by the Crossvent is within ±10% of the actual flow, in this case 4.5 – 5.5 lpm, proceed with the next flow point in the table. If it is not within the 10% limits, press the "5" key in the table corresponding to the actual flow. The displayed flow on the Crossvent should now display 5 lpm. The flow knob is now calibrated to the actual flow for that setting. Repeat for all other flow points while holding a PEEP of 15 cmH_2O as described previously.

15. PRESSURE CALIBRATION

TO TEST:

a. Tee a 10-25 ml syringe (or similar) into a tube that connects the airway pressure fitting on the Crossvent to a low pressure test device.

b. Turn on the Crossvent.

c. While pushing in and varying the plunger on the syringe, observe the pressure bar graph and PEAK reading above the graph.

d. The readings on the display should be within 3% of the readings on the test instrument. If not within specification, refer to Troubleshooting in the following section before proceeding to calibration.

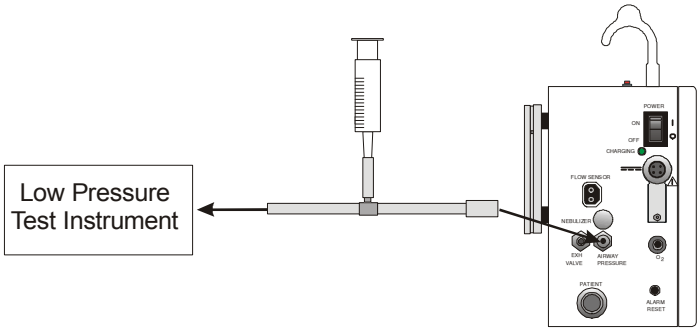


FIG. 14- PRESSURE CALIBRATION

IF IT FAILS THE ABOVE TEST, CALIBRATE AS FOLLOWS:

e. Turn the unit on and press SETUP and then the CAL MENU key.

f. Press the PRESSURE key and enter the authorization code.

g. With the airway pressure connector on the side of the unit open to atmosphere (zero pressure), press the key labeled ZERO.

h. Set up as in step a.

i. Apply 100 cmH_2O pressure to the airway pressure connector and press the 100 cmH_2O key.

G- DISASSEMBLY & REASSEMBLY INSTRUCTIONS

WARNING: High voltage is present at the backlight connector (JBL) when power is on.

CAUTION: All safety measures must be observed when servicing this device. In particular, the ventilator must be turned off and the power supply disconnected.

CAUTION: With the PC Board removed, great care should be taken to protect the board from stray voltages, static electricity, and any other environmental concerns that may damage the board. Always handle the board with care and be sure you and your work surface are properly grounded.

Note: Prior to disposal of any component, with particular attention to the battery and PCB, check with your local controlling authority for disposal regulations.

1. REAR PANEL

1. Remove the four (4) long screws located around the perimeter of the rear panel. These extend to the front bezel.
2. Remove the rear panel.
3. Reverse order to re-install. Be sure the battery cable grommet is set properly into the notch in the battery compartment and no other wires or tubes are in a position to be pinched when the panel is installed.

2. BATTERY REMOVAL & REPLACEMENT

CAUTION: Only replace the battery pack with Bio-Med Devices part #PRT4467. Do not substitute.
NOTE: After installing a new battery, it must be discharged, the battery gauge must be reset in the calibration menu and the battery then fully charged as outlined in this procedure.

1. Remove the rear panel.
2. Remove the grommet on the battery wires from the notch in the battery compartment and lift the battery out of the battery enclosure. Unplug the battery connector.
3. Verify four 1/16" rubber pads similar to those supplied with the new battery are adhered to the bottom (side closest to the PC Board) of the battery enclosure. Replace any that are missing with those supplied so that they will be under the center of each corner cell of the battery pack when it is installed. There should also be two 1/8" thick pads on the inside of the rear panel within the cutout in the battery enclosure gasket. Replace any that are missing as illustrated here.
4. Place the battery in the enclosure so that the label on the battery is facing the rear panel.
5. Plug the connectors together outside the enclosure and work the grommet on the wire into the notch in the side of the enclosure.

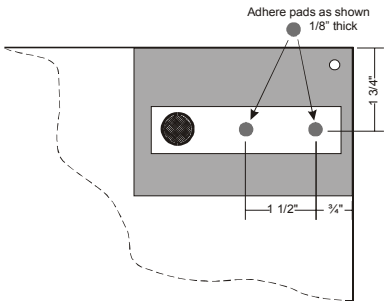


FIG. 15- BATTERY PADS

6. Replace the rear panel and four screws. Take care that the grommet remains in the notch when the panel is replaced and no wires or tubing are pinched.

If this is a new battery or a battery other than the original battery, then proceed with the following steps to discharge the battery, zero the gauge and then recharge the battery. This must be done to re-program the battery gauge to the newly installed battery.

7. Turn on the Crossvent. Be sure the external power supply is not connected to the unit. If the unit will not power on without the external power supply, then go to Step 11.
8. When the MAIN menu appears, press the SETUP key in the lower right of the display and then press the CAL MENU key.
9. Press VALVES and turn each valve on by pressing OFF next to them.

10. Leave the unit like this until the battery is expended and the unit turns itself off.
11. Plug the Bio-Med Devices external power supply into the side of the unit. This plug and jack are keyed so the red dot on the plug must be facing the front of the unit in order for them to engage. Power on the unit by first turning the ON/OFF switch to OFF and then back to ON.
12. Press the SETUP key and then the CAL MENU key.
13. Press BATTERY, press CONTINUE and enter the authorization code.
14. Press the key labeled RESET. This will change to green indicating the gauge has been zeroed.
15. Turn the unit off and allow it to charge the battery fully. This may take up to five hours.
16. When the Charging LED stops blinking, the battery will be fully charged. Unplug the external power supply, turn on the unit and verify the battery gauge indicates a full battery.

    NOTE: If RESET changes to red when pressed, there has been an error. Press the key again. If it is continually red, then there is a problem with the battery gauge chip, IC202, or communication between this chip and the microprocessor.

3. FRONT BEZEL

1. Remove the rear panel.
2. Disconnect and remove the battery or, in lieu of removal, the battery may be held in place with tape.
3. Place the Crossvent on its back with the bezel facing up.
4. While holding down on the case, pull up on the edges of the bezel, first one side and then the other, working from one side to the other until it is free. The knobs that are pressed onto the valve shaft extenders cause the resistance to removal. The knobs will come off with the bezel as it is removed. Be aware that the RFI gaskets may come off as the bezel is removed. Retain them for reinstallation.
5. To re-install, make sure the RFI conductive gaskets are in place on the outside edges of the bezel as well as around the display window. Also be sure the amplifying tube for the beeper on the PCB is positioned properly behind the alarm holes in the front of the bezel. Then place the bezel over the valve shaft extenders and fit it into the case.
6. Press the knobs back on the extenders, turn the unit over and proceed in reverse order as before.

4. DISPLAY/TOUCHSCREEN

Warning: High voltage is present at the backlight connector (JBL) when the power is on.

1. Remove rear panel.
2. Disconnect and remove the battery or, in lieu of removal, the battery may be held in place with tape.
3. Remove the Bezel.
4. The display/touchscreen is connected to the PCB on the left side with two ribbon cables (some may have one), on the right side with one connector to the backlight, and underneath by one ribbon cable. Unplug the display/touchscreen on its left side where it connects to the PCB and separate the backlight plug on the right side. Leave the ribbon cable underneath to the display plugged into the PCB at this point.
5. There are two clamps diagonally opposed to one another on the standoffs for the display. Disengage these.
6. Carefully lift the display/touchscreen assembly straight up and away from the PCB just until it separates from the PCB.
7. With the display separated from the PCB, tilt it slightly by lifting the right side and unplug the ribbon cable from the PCB.
8. Re-install in reverse order.
9. If this is a new assembly, then refer to the Touchscreen calibration procedure in Part A-2 of this section to calibrate the touchscreen once the unit is back together.

5. POPULATED CIRCUIT BOARD (PCB)

See Cautions at the beginning of this section.

1. Set the MAX Pressure and PEEP knobs fully off (CCW).
2. Remove the rear panel, battery and front bezel.
3. From the rear of the unit, unplug the tubes from the transducer(s).
4. Unplug the cable from the solenoid board to the PCB.
5. Unplug the pressure sensor switch and remove the two nuts that secure it to the battery enclosure. Taking care not to damage or kink the tube on the pressure switch, remove the switch from the threaded studs and hold it off to the side in order to unplug the Flow Sensor connector (JPNEUMO) underneath it.
6. Once the Flow Sensor is unplugged, secure the pressure switch back in place. There is no need to tighten the nuts at this time as they will have to be removed for reinstallation of the PCB later.
7. Unplug the cable from the RS232 board to the PCB.

8. Unplug the O_2 jack.
9. From the front, unplug the potentiometer cable (JPOT), alarm LED cable (JLED) and Entrainment switch cable (JETRAIN), if present.
10. Loosen the inside nut on the power connector on the left side of the case and then remove the external round nut.
11. Remove the four corner screws and lock washers securing the PCB to the case.
12. To remove the PCB, it should be raised at an angle by lifting the edge opposite the power connector until the PCB clears the valve shafts and then extract it from the power side of the case. The washer on the power jack will be loose.
13. When re-installing, be sure the inside hex nut and the washer are on the power connector before inserting the connector through the side of the case. The washer should be outside of the nut so it will be against the case. Taking care not to pinch any wire harnesses, angle the PCB so it is under the O_2 sensor jack and the power connector protrudes through its hole in the case and then lower the PCB over the valve shafts.
14. Check the gaskets on the power side of the case. The PCB should be underneath those that are double thick.
15. Align the mounting holes to the case and install the four mounting screws, but do not tighten these screws at this time.

If the round external nut for the power connector has a dimple in it, then skip to Step 17. Otherwise continue with the next step.

16. Nut without dimple- Turn the inside nut on the power connector until it captures the lock washer snuggly against the case.
17. Thread the round external nut onto the connector, shoulder first. With the shoulder inside the opening for the connector, tighten this nut while holding the internal nut stationary. Be careful during this process that the PCB remains properly aligned to the mounting holes. Go to Step 19.
18. Nut with dimple- Thread the round nut, shoulder first, onto the power connector until the face of the nut is flush, or nearly so, with the leading edge of the connector, its shoulder is within the opening in the case and the dimple is aligned with the small notch on the inside wall of the connector (3:00 o'clock position as viewed from the side with the unit upright).
19. Turn the inside nut on the power connector until it captures the lock washer tightly against the case. Be careful during this process that the PCB remains properly aligned to the mounting holes.
20. Tighten the four PCB mounting screws.
21. Continue with the installation in reverse order of removal.

6. COMPLETE PNEUMATICS AS AN ASSEMBLY

Removing all of the pneumatics is usually not required for any servicing, but may be deemed necessary for other reasons such as full case replacement. Make a note of tube routing as they are cut or removed to facilitate reassembly.

.

1. Remove rear panel, battery, front bezel and PCB
2. Remove the two screws at the bleed exhaust screen next to the gas supply fitting. This will free the 9-port bleed manifold inside the case. Watch for the o-ring inside this manifold. Do not misplace this if it should fall out.
3. Remove the external gas supply input fitting and remove the filter that will be exposed once this fitting is removed. When reinstalling, align the inside hex fitting on the regulator with the opening in the case, insert the filter (cone to the outside) and thread in the outside fitting. It is best to hold the inside hex with a second wrench while tightening the outside fitting as these must be very tight to seal the filter and fittings.
4. If the unit has Air Entrainment installed, then loosen the setscrews holding the knob on the Entrainment Switch, remove the knob and remove the switch's retaining nut. Push the switch through the case.
5. On the opposite side of the case, locate the manifold (small block with relief valve) into which the patient connector threads. From the back of the unit, there is a setscrew recessed into this manifold. Using a 1/16" hex key, loosen this setscrew. The patient connector may now be unscrewed. Watch for a gasket between the manifold and connector. When reassembling, do not over-tighten this connector or the gasket will distort. Thread it in until it is seated and then turn it another half turn and secure it with the setscrew.
6. Cut the tubing (brown) to the exhalation valve fitting on the side of the case. Do this as close to the fitting as possible to leave as much tubing as possible. If tubing is to be reattached to this fitting when reassembled, carefully cut off the tubing left on the barb, taking care not to damage or

nick the barb (refer to Fig. 16 in Preventive Maintenance Kits later in this section). This is easiest to do after the pneumatics have been completely removed.

7. Tubing from the MAX Pressure valve is routed between the case and the rear panel screw guide on the side of the case. Work these tubes out from behind this guide.
8. Remove the three screws from the bottom of the case. These retain the pneumatic bracket assembly.
9. Although not necessary, the RS232 connector may be removed from the side of the case to facilitate removal of the solenoid assembly. To remove it, remove the single retaining screw. The lower corner snaps onto a stud. Pry it off this stud and remove the part.
10. Unplug the Pressure Sensor Switch from the PCB and remove the two nuts and lock washers used to retain the solenoid manifold assembly to the top of the case and lower the assembly off the studs.
11. Remove the two nuts with washers that retain the supply pressure sensor to the bottom of the battery compartment. When everything is removed, take care the thin tubing to this sensor is not damaged.
12. The pneumatics are now free from the case and may be removed.
13. Reassemble in the reverse order.

7. PNEUMATIC VALVE BRACKET ASSEMBLY

1. Remove rear panel, battery, and front bezel. It is not necessary to remove the PCB to remove the Valve Bracket, but it may be easier if it is removed. This instruction assumes it is not removed.
2. Unplug the potentiometer from the front of the PCB (JPOT) as well as the Entrainment Switch connector (JETRAIN), if present.
3. From the outside of the Crossvent, remove the two screws at the bleed exhaust screen next to the gas supply fitting. This will free the 9-port bleed manifold inside the case. Watch for the o-ring inside this manifold. Do not misplace this if it should fall out.
4. It is best to remove the Pressure Regulator along with the bracket so the tubing between it and the Flow Valve are not disturbed. To remove the regulator, unscrew the supply fitting on the outside of the case and remove it along with the filter inside. The regulator is now free from the case and will come out with the bracket assembly.
5. If the unit has Air Entrainment installed, then loosen the setscrews holding the knob on the Entrainment Switch, remove the knob and remove the switch's retaining nut. Push the switch into the case.
6. On the opposite side of the case, locate the manifold (small block with relief valve) into which the patient connector threads. From the back of the unit, there is a setscrew recessed into this manifold. Using a hex key, loosen this setscrew. The patient manifold may now be unscrewed. Watch for a gasket between the manifold and connector. When reassembling, do not over-tighten this connector or the gasket will distort. Thread in until it is seated and then turn it another half turn and secure it with the setscrew.
7. Tubing from the MAX Pressure valve is routed between the case and a rear panel screw guide on the side of the case. Work these tubes out from behind this guide.
8. Prior to cutting any tubing, always make a note of its location or label it for reference when reassembling. Cut this tubing as close to the barb as possible-
    a. Yellow tube on MAX Pressure Valve (22, Fig. 10).
    b. Yellow tube on DARV Manifold (10/10A)
    c. Blue tube from the PEEP Variable Resistor (131). Cut where it connects to the tee with the yellow tube.
    d. Green tube at the pressure sensor located on the battery enclosure.
    e. Green tube from the bottom of the regulator to the solenoid manifold. Cut at the manifold barb.
    f. Clear tube to the manifold at solenoid A. Cut at the manifold barb.
    g. Clear tube from the regulator to the Flush Variable Resistors (132). Cut at the tee.
9. Cut the cable tie and remove the 1/8" tube from the check valve between the regulator and the 9-port manifold.
10. Remove the three screws on the bottom of the Crossvent. The bracket along with the regulator can now be removed. Pull it straight back while guiding the potentiometer cable (and Entrainment Switch cable) under the PCB.

Reassemble in the reverse order. Prior to reassembling, carefully cut off the tubing left on any barbs, taking care not to damage or nick the barbs (refer to Fig. 16 in Preventive Maintenance Kits later in this section).

8. FLOW, MAX PRESSURE & PEEP VALVES

1. Remove the rear panel, battery, front bezel and PCB. In lieu of removing the PCB, the Pneumatic Valve Bracket assembly can be removed to access the valves.
2. **FLOW VALVE**

   WARNING: Any time the flow valve(s) are disturbed, the flow calibration in the CAL menu must be performed. Refer to the Pneumatic Calibration section.

   a. From the rear of the unit, cut the tubing from the flow valve barb to the Regulator/Pilot Valve. Take care not to damage or nick the barb.
   b. From the front, rotate the gear on the Flow Valve until the setscrews can be accessed. There will be two setscrews per hole, one on top of the other, for a total of four. Remove the top setscrews and then loosen the ones underneath. Remove the gear.
   c. Remove the retaining nut and washer from the front of the valve.
   d. Slide the valve towards the potentiometer to disengage the brass connecting tube to the DARV Manifold and remove the valve.
   e. To replace the valve, first turn the valve shaft CW until slight resistance is felt indicating it is closed and place a very light film of oxygen-safe grease on the o-ring at the end of the connecting tube. From the rear of the bracket, insert the valve shaft through the open slot in the bracket and position the valve so the raised shoulder on the front of the valve is in the slot and the brass connecting tube is aligned with the hole in the side of the DARV Manifold.
   f. Slide the valve towards the DARV Manifold so the o-ring on the brass connecting tube engages the hole in the DARV.
   g. Place the washer over the threads on the front of the valve and then thread on the nut loosely so the valve can still be moved within the slot.
   h. The valve must now be positioned in the slot for proper engagement with the gear on the potentiometer. Place the Flow Valve gear on the shaft of the Flow Valve and temporarily tighten one setscrew just enough to hold the gear in place.
   i. To aid in establishing an acceptable engagement of these two gears, place a small strip of paper (standard copier paper approx. 5-6 mil thick) between the gears and slide the valve towards the potentiometer until the gears mesh snugly with the paper formed around the teeth between them.
   j. Hold the valve in this position within the slot, remove the gear and tighten the retaining nut. Be careful the valve does not move within the slot.
   k. Remove the gear from the potentiometer shaft. Within the gear teeth there will be two setscrews per hole, one on top of the other, for a total of four. Remove the top setscrews and then loosen the ones underneath. Remove the gear.
   l. Rotate the Flow Valve shaft 180° CCW from the closed position.
   m. Position the gear on the shaft so that the setscrews are at the top (approximately 11 & 1 o'clock positions) and secure the gear to the shaft by tightening the setscrews and replacing the second setscrews. Turn the valve CW back to the off position. The setscrews should now be at the bottom.
   n. From the Pilot Valve, remove the remaining clear tubing that was previously cut from the Flow Valve. Be careful not to damage or nick the barb.
   o. Replace this tubing between the Pilot Valve and Flow Valve with a new piece and tighten a cable tie around each barb for added security.
   p. To properly secure the potentiometer gear to the valve shaft, refer to the Pneumatic Calibration section and perform Flow Valve/Potentiometer Zero, skipping the "To Test" and going right to the "Calibrate as follows" section. Once this has been completed, reassemble the rest of the unit and then proceed to the Flow Calibration in the Pneumatic Calibration section.

3. **ENTRAINMENT FLOW VALVE**

   a. <u>Only do this step if the valve is to be replaced.</u> Carefully cut each of the 9 tubes from the valve to the venturi block at the block end. Cut the supply tube at the elbow in the rear of the valve.
   b. From the front, rotate the valve gear until the setscrews in the gear can be accessed. There will be two setscrews per hole, one on top of the other, for a total of four. Remove the top setscrew and then loosen the one underneath. Remove the gear.
   c. Remove the nut and washer and remove the valve from the bracket.
   d. If the tubing to the venturi block was cut in step b, then carefully remove any remaining tubing from the barbs on this block. Do not nick or damage the barbs in any way while doing this (refer to Fig. 16 in Preventive Maintenance Kits later in this section).
   e. Before installing the new valve, locate the line or mark on the side of the valve. This indicates the #1 port, which is the barb adjacent to this mark. Install the valve into the bracket so this mark is facing the battery compartment (facing up).

f. Making sure the valve is properly centered in the bracket slot, place the washer and nut on the valve and secure the valve so it is held in place, but still can be moved back and forth within the slot.
g. Turn the elbow fitting in the back of the valve so it is directed down, reconnect the supply tube and secure it with a cable tie.
h. Starting with the tube on port 1 (next to the mark) on the valve, push the open end of this tube onto the barb on the venturi that is in the top row and closest to the front of the unit.
i. The next tube to connect will be port 2. This is the barb directly to the left of the port 1 barb (CCW as viewed from the rear). Connect this to the bottom barb closest to the front of the unit on the venturi block.
j. Continue connecting the tubes from the valve to the venturi, moving in a counterclockwise direction around the valve and front to rear, alternating top to bottom, on the venturi until all the tubing has been connected.
k. The valve must now be positioned in the slot for proper engagement with the gear on the potentiometer. Place the Flow Valve gear on the shaft of the Entrainment Flow Valve and temporarily tighten one setscrew just enough to hold the gear in place.
l. To aid in establishing an acceptable engagement of the gears, place a small strip of paper (standard copier paper approx. 5-6 mil thick) between the gears and slide the valve towards the potentiometer until the gears mesh snugly with the paper between them.
m. Hold the valve in this position within the slot, remove the gear and tighten the retaining nut to lock the valve in this position. Be careful the valve does not move within the slot.
n. Refer to the Calibration section on Flow Valve/Potentiometer Zero as well as the one on Flow (Entrainment on) for instruction on properly zeroing the valve, securing the gear and calibrating the valve.

4. **MAX PRESSURE & PEEP VALVES**

The procedure for either of these valves is the same.

a. Loosen the two setscrews in the valve shaft extender and remove the extender,
b. Remove the retaining nut and withdraw the valve from the bracket, making note of the orientation of the barbs as they were when mounted.
c. Taking note of which color tube goes to each barb, cut the tubing from the barbs on the valve as close to the barb as possible.
d. To install, press the appropriate tubing onto each barb and install the valve into the bracket with the barbs positioned as previously noted.
e. Secure with its nut.
f. Refer to the Pneumatic Calibration section on PEEP Valve Zero and MAX Pressure Valve Zero for instructions on reinstalling the valve extender and then check the PEEP Signal and MAX Pressure Signal calibration.

9. SOLENOIDS

See Cautions at the beginning of this section.

1. Remove the rear panel and battery.
2. Remove the RS232 connector from the inside of the case by unplugging the cable and removing the single retaining screw. The lower corner snaps onto a stud. Pry it off this stud and remove the part.

14.

3. Remove the two Solenoid Manifold retaining nuts and washers and lower the assembly off its mounting studs.
4. Position the assembly so the component side of the Solenoid PCB is facing you.
5. Locate the solenoid pins on the PCB. They will have resistors across them. Carefully de-solder all the solenoids. Remove the two screws holding the board to the manifold and separate the PCB from the solenoids.
6. Unscrew the two screws holding the solenoid to be replaced to the manifold and remove the solenoid.
7. Making sure the gasket is properly fitted around the new solenoid's ports, secure it to the manifold with the screws.
8. With the component side facing away from the solenoids, place the Solenoid PCB over the solenoid pins and secure it to the manifold with the two screws.
9. Re-solder each solenoid to the Solenoid PCB and reassemble in reverse order.

10. ENTRAINMENT ON/OFF SWITCH

The Entrainment ON/OFF Switch is not serviceable and its removal is straightforward. The following describes replacement of the micro-switch mounted to the ON/OFF switch.

1. Remove the rear panel and battery.
2. Turn the knob on the outside of the case to the ON position.
3. Unplug the Entrainment Switch cable (JENTRAIN) from the front of the PCB, remove the two screws retaining the micro-switch and remove it.
4. Mount the new switch so that the plunger is directly under the cam on the shaft of the ON/OFF switch.
5. Connect an ohmmeter to the micro-switch cable and observe continuity as the On/OFF knob is positioned from ON to OFF and OFF to ON. The micro-switch should be open when in the OFF position and closed when ON. If it does not meet these criteria, loosen the setscrew in the cam above the micro-switch and reposition the cam so it does.
6. Reinstall the battery and rear panel.

11. GAS INPUT FILTER

1. Remove the Rear Panel. Be careful of the battery, which is now free. It may be secured by taping it in place or it may be removed.
2. Remove the two exterior screws at the bleed exhaust screen next to the gas supply fitting. This will free the 9-port bleed manifold inside the case. Move this manifold to the side so a wrench can engage the hex fitting on the regulator behind it. Watch for the o-ring inside this manifold. Do not misplace this if it should fall out.
3. Hold the large hex fitting on the regulator from turning with one wrench and use a second wrench to unscrew the outside supply fitting.
4. Remove the conical filter that is inside these fittings and replace it with a new one.
5. Reassemble in the reverse order. Be sure to tighten these fittings enough to seal the filter (approximately 25 foot-pounds [3.5 kg]).
6. If this Crossvent has the Entrainment feature, there will be a second filter which is located in the venturi assembly. Remove the black ring around the venturi inlet and replace the filter within. Replace the ring.

12. PREVENTIVE MAINTENANCE KITS

1. The simplest way to replace the pneumatic logic lines is to do them one line, one point at a time.
2. Once all the logic lines in the kit have been replaced, they will need to be calibrated. Refer to the Pneumatic Calibration Procedures for these instructions.
3. The process for removal and replacement is the same for each line as described here.
   a. Observe the new logic line and locate the existing matching line in the Crossvent. Study how it is installed and where each end is connected.
   b. It does not matter which end you start with so pick an end on the new line and match it up with the line to be replaced.
   c. Using a sharp X-acto style knife, remove the tube from the barb by slicing it along the length of the barbed fitting starting at the base and stopping at the barb (see illustration). It is important not to damage the actual barb in any way or a gas leak may occur after reassembly.
   d. Using needle nose pliers, grab the cut tubing and peel it back and remove it from the fitting.
   e. Push the matching end of the new line onto the barbed fitting with the needle nose pliers being careful not to damage the tubing in the process. Push it on far enough to reach the base of the barb.
   f. Repeat this process for each end of the new line, one at a time, until the old line is completely removed and the new one is completely installed.
   g. When done, ensure that no part of the pneumatic logics can make contact with the PCB. Use cable ties if necessary, but use them loosely.
   h. Before the Crossvent can be returned to service, these parts must be calibrated as outlined in the Pneumatic Calibration section.

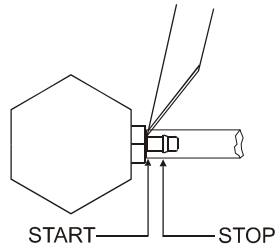


FIG. 16- CUTTING TUBE

H- TECHNICAL TROUBLESHOOTING CHART

NOTE: A performance test should always be completed before proceeding with repairs.

CAUTION: Always follow proper static grounding procedures when removing or replacing electronic parts, LCD assembly, etc.

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Audible alarm with no visible indication	Hardware Failure	Refer to Appendix E
Auto cycling of the ventilator.	Pressure out of calibration. Pressure Trigger set too low.	Re-cal pressure. Increase Pressure Trigger setting.
Battery low audible and visual alarm.	Low battery.	Charge battery.
Battery will not charge. External power ok.	Battery open. Battery internal fuse open due to heat or short Battery cable open D101, D104, DC101 open	Replace battery. Allow to cool or replace battery Repair cable. Replace defective part
No battery operation.	Battery not charged. D103 or DC103 open.	Charge battery. Replace D103 or DC103.
External power failure alarm – "BATT" flashing.	Loss of external power. AC adaptor defective. Fuse F101 open. Defective D101, D104, DC101	Check input mains. Replace ac adaptor. Change fuse F101. Replace defective part
Ventilator will not power up from external power. Battery operation ok.	Fuse F101 open. AC adaptor defective. D101, DC101 or D104 open.	Replace F101. Replace AC adaptor. Replace defective part.
Ventilator fails key test. All other functions normal.	Defective touchscreen. Bad IC401. Poor Connection at JTS	Replace touchscreen. Replace IC401. Reconnect JTS or return to factory.
Ventilator fails display test.	Poor connection at JLCD. Defective LCD. Defective IC403.	Reconnect JLCD Replace LCD. Replace IC403.
No Display	Bad connection at JLCD or JBL Defective LCD Defective IC403 or Inverter	Correct connection Replace LCD Replace defective part

SYMPTOM	POSSIBLE CAUSE	CORRECTIVE ACTION
Oxygen will not calibrate.	Aged sensor. Bad IC602, L301 (no +5V analog) Bad cable.	Replace sensor. Replace IC602, L301. Replace cable.
Pressure will not calibrate.	Tubing leak. TD-AIRWAY bad.	Replace tubing. Replace TD-AIRWAY.
Pressure unable to reach 120 cmH_2O during operation.	Loosing pressure through Pressure Relief Valve. DARV leaking at seat or signal pressure.	Clean, re-cal or replace Relief Valve. Clean seat, repair leak, re-cal or replace.
Flow will not cal. (See following symptom also)	Bad connection at JPOT Defective flow encoder. Bad IC603. Defective atmospheric compensation circuit.	Reconnect Replace 10K pot. Replace IC603. Check TD-ATMOS.
Flow will not reach 120 LPM or displayed flow does not agree with actual flow.	Supply pressure too low. Max Pressure not on or defective. Flow restriction or leak. Input filter clogged. Regulator set too low. Flow valve defective.	Check supply pressure at ventilator input fitting while gas is flowing. Should meet specification on side of case. Turn Max Pressure fully on or repair. Check for restrictions and leaks in flow path. Replace filter and resolve cause Calibrate regulator pressure. Check flow valve.
VENTILATOR FAILURE flashes on display	Refer to Appendix E	Replace solenoid. Replace solenoid wire. Power off/on. If persists, then return to factory for service.
Pneumotach reading greatly inaccurate	Leak in breathing circuit Bad transducer (TD-PNEUMO)	Check all circuit connections Replace transducer and/or check associated circuitry
Unit hangs with Bio-Med Devices on the display	Microprocessor failure	Return to factory
Continuous Audible Tone	Devices controlling the alarm beeper have failed.	Return to factory

X. PARTS LIST AND SCHEMATIC DIAGRAMS

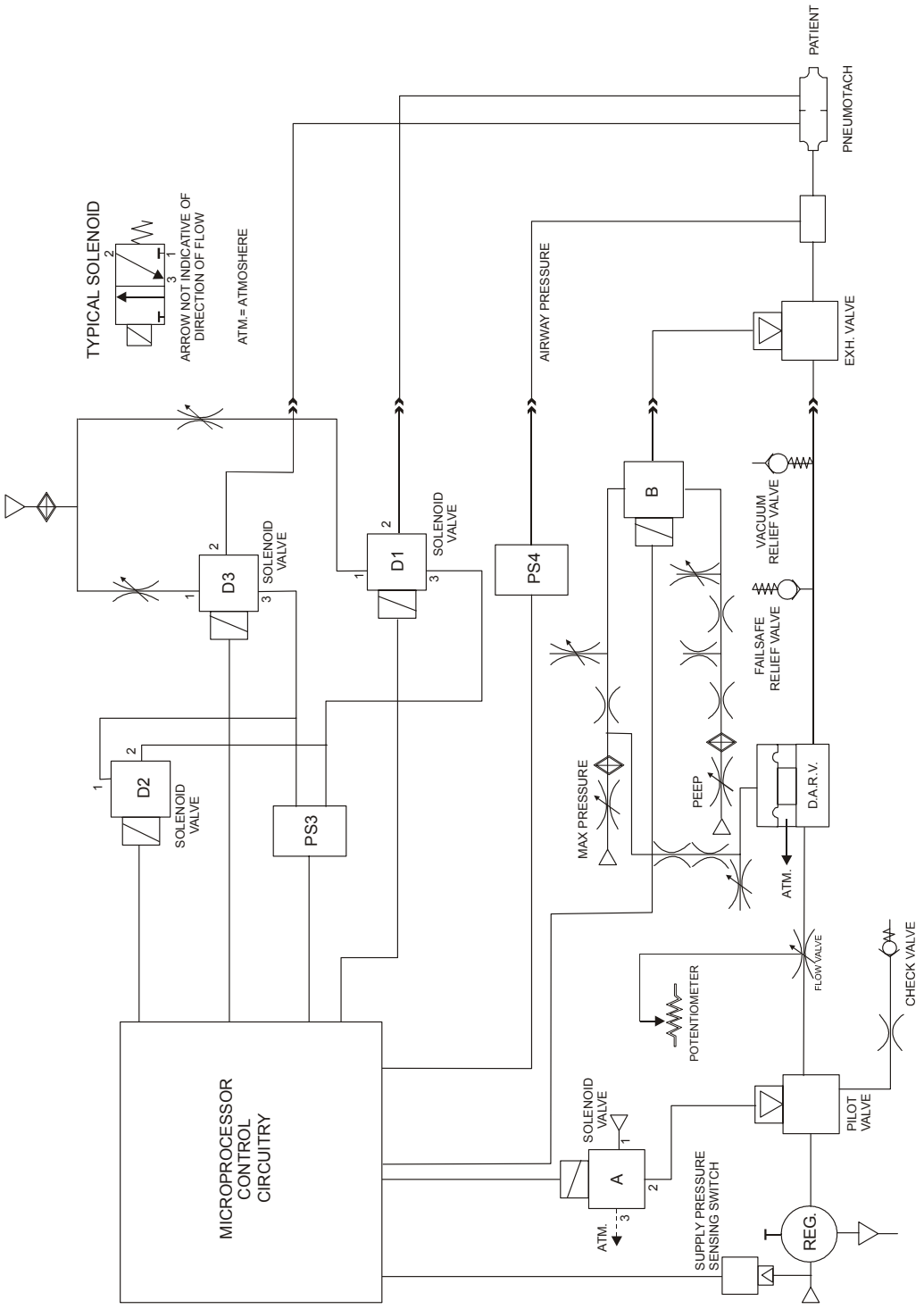
A- REPLACEMENT PARTS LIST

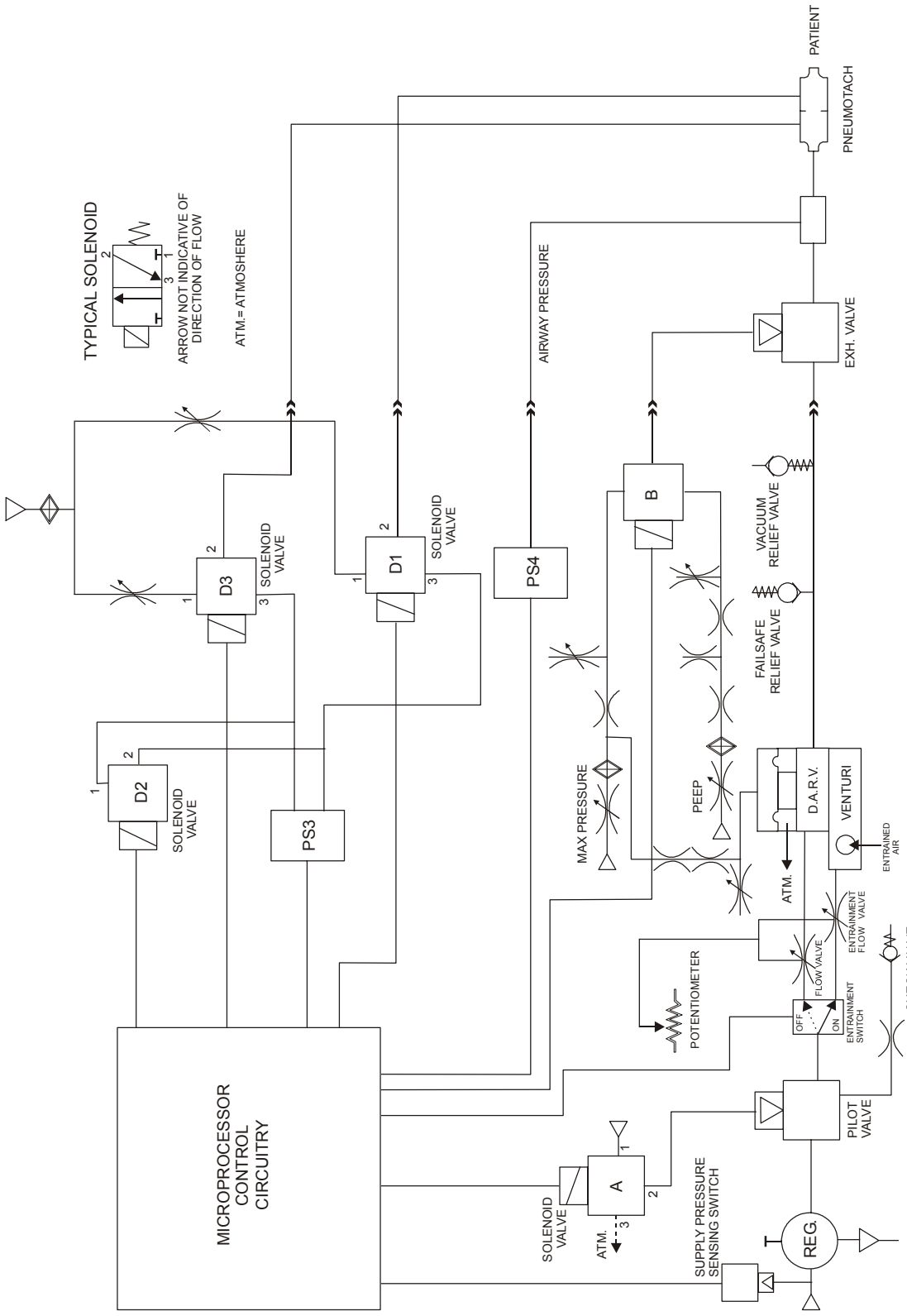
NOTE: SERIAL NUMBER OF VENTILATOR **MUST** ACCOMPANY ALL PARTS ORDERS

ITEM	PART #	DESCRIPTION
1	PRT3348	KIT, PREVENTIVE MAINTENANCE (UNITS WITHOUT FLOW SENSOR AND WITHOUT ENTRAINMENT)
2	PRT3350	KIT, PREVENTIVE MAINTENANCE (UNITS WITHOUT FLOW SENSOR BUT WITH ENTRAINMENT)
3	PRT3353	KIT, PREVENTIVE MAINTENANCE (UNITS WITH FLOW SENSOR BUT WITHOUT ENTRAINMENT)
4	PRT3354	KIT, PREVENTIVE MAINTENANCE (UNITS WITH FLOW SENSOR & ENTRAINMENT)
6	PRT4467	BATTERY PACK, 6 D CELL NiMH (Do not substitute)
12	PRT3316	ASSY, LCD/TOUCHSCREEN DISPLAY
13	PRT4410	LED, ALARM
15	PRT3318	PC BOARD FOR UNITS WITH FLOW SENSOR- NO DISPLAY INCL'D*
15A	PRT3319	PC BOARD FOR UNITS WITH FLOW SENSOR- DISPLAY INCL'D*
16	PRT3322	PC BOARD FOR UNITS WITHOUT FLOW SENSOR- NO DISPLAY INCL'D*
16A	PRT3323	PC BOARD FOR UNITS WITHOUT FLOW SENSOR- DISPLAY INCL'D*
23	EVAL006	SOLENOID
29	4419A	CHARGER w/US HOSPITAL-GRADE CORD (Do not substitute)
30	4419B	CHARGER w/EURO UNTERMINATEDCORD (Do not substitute)
32	PFIL008	FILTER, CONICAL SUPPLY
141	PRT3317	PRESSURE SENSING SWITCH

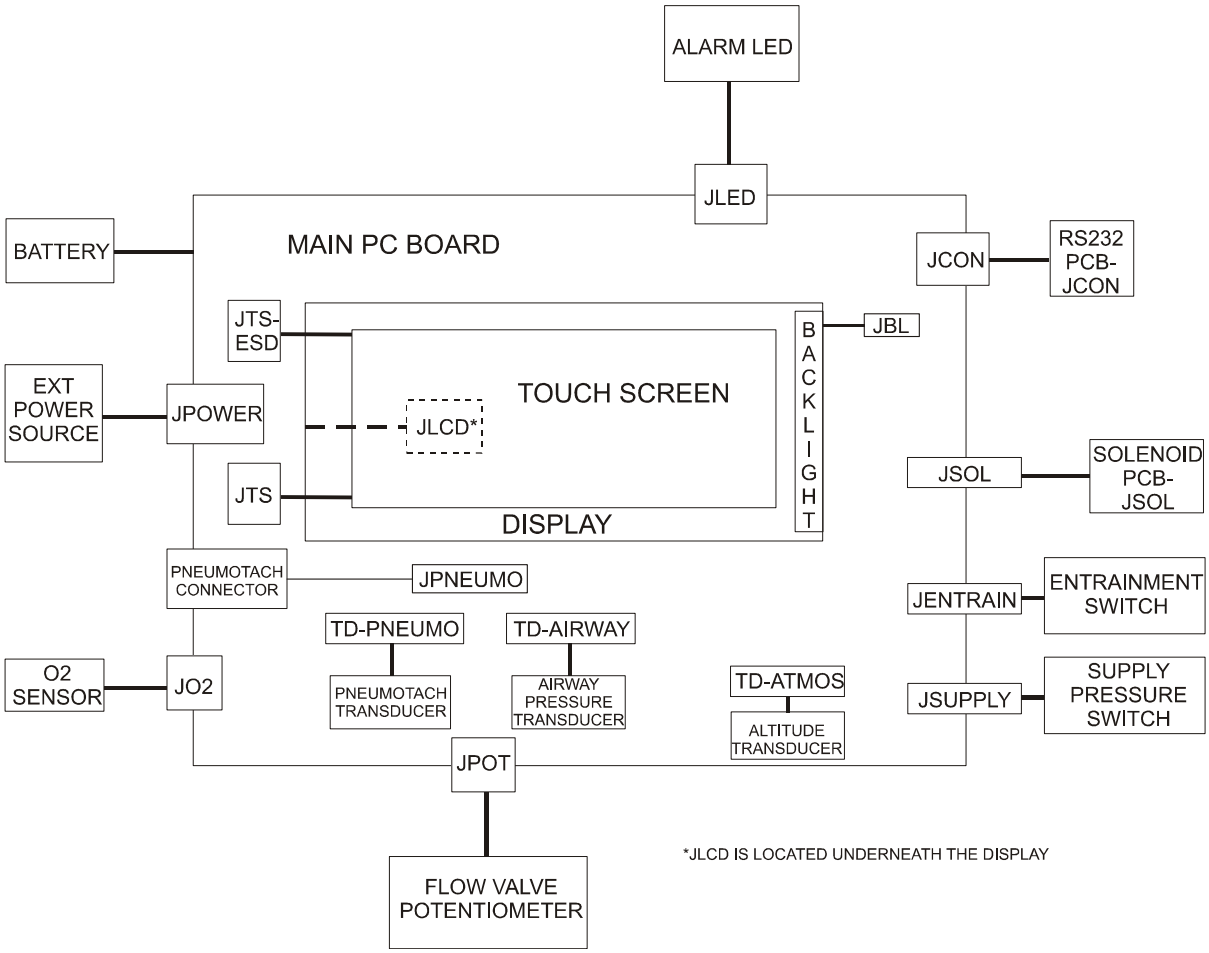
B- SCHEMATICS

1- PNEUMATIC SCHEMATICS

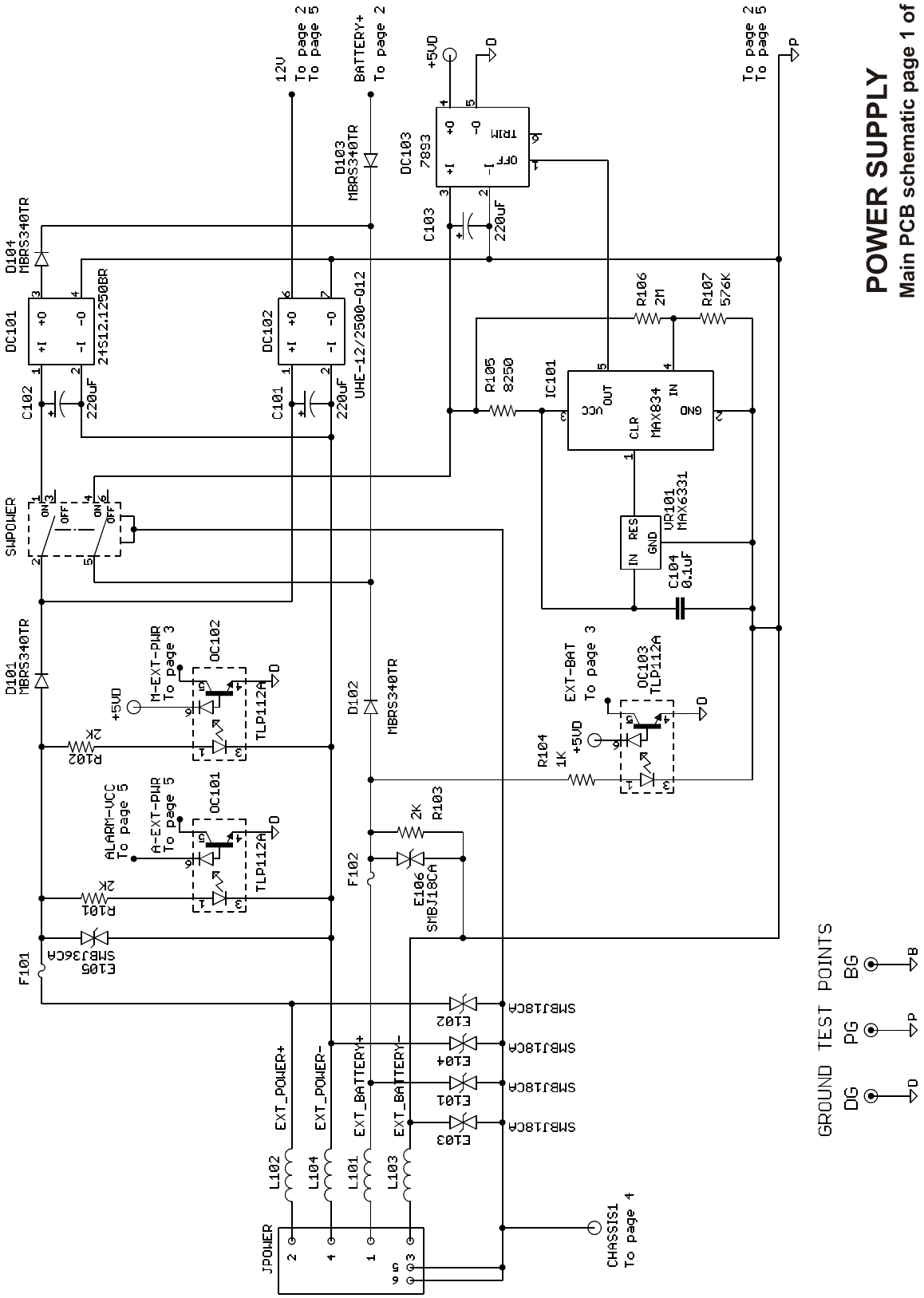


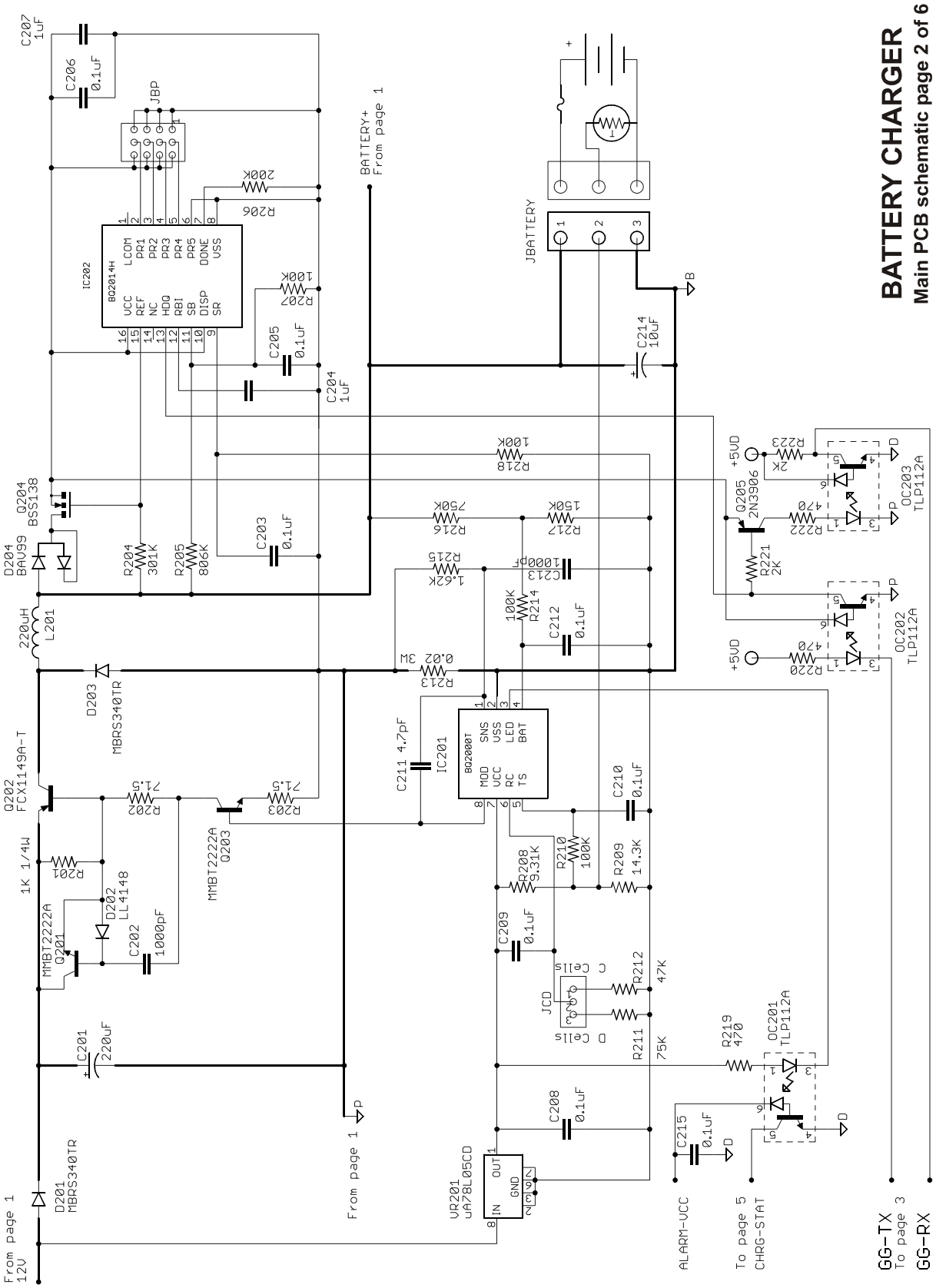

PATIENT
PNEUMOTACH
EXH. VALVE
AIRWAY PRESSURE
TYPICAL SOLENOID
ARROW NOT INDICATIVE OF DIRECTION OF FLOW
ATM.= ATMOSHERE
D3
SOLENOID VALVE
D1
SOLENOID VALVE
PS4
B
VACUUM RELIEF VALVE
FAILSAFE RELIEF VALVE
D2
SOLENOID VALVE
PS3
MAX PRESSURE
PEEP
D.A.R.V.
VENTURI
ENTRAINED AIR
ATM.
ENTRAINMENT FLOW VALVE
FLOW VALVE
POTENTIOMETER
OFF
ON
ENTRAINMENT SWITCH
CHECK VALVE
MICROPROCESSOR CONTROL CIRCUITRY
PILOT VALVE
SOLENOID VALVE
A
ATM.
SUPPLY PRESSURE SENSING SWITCH
REG.

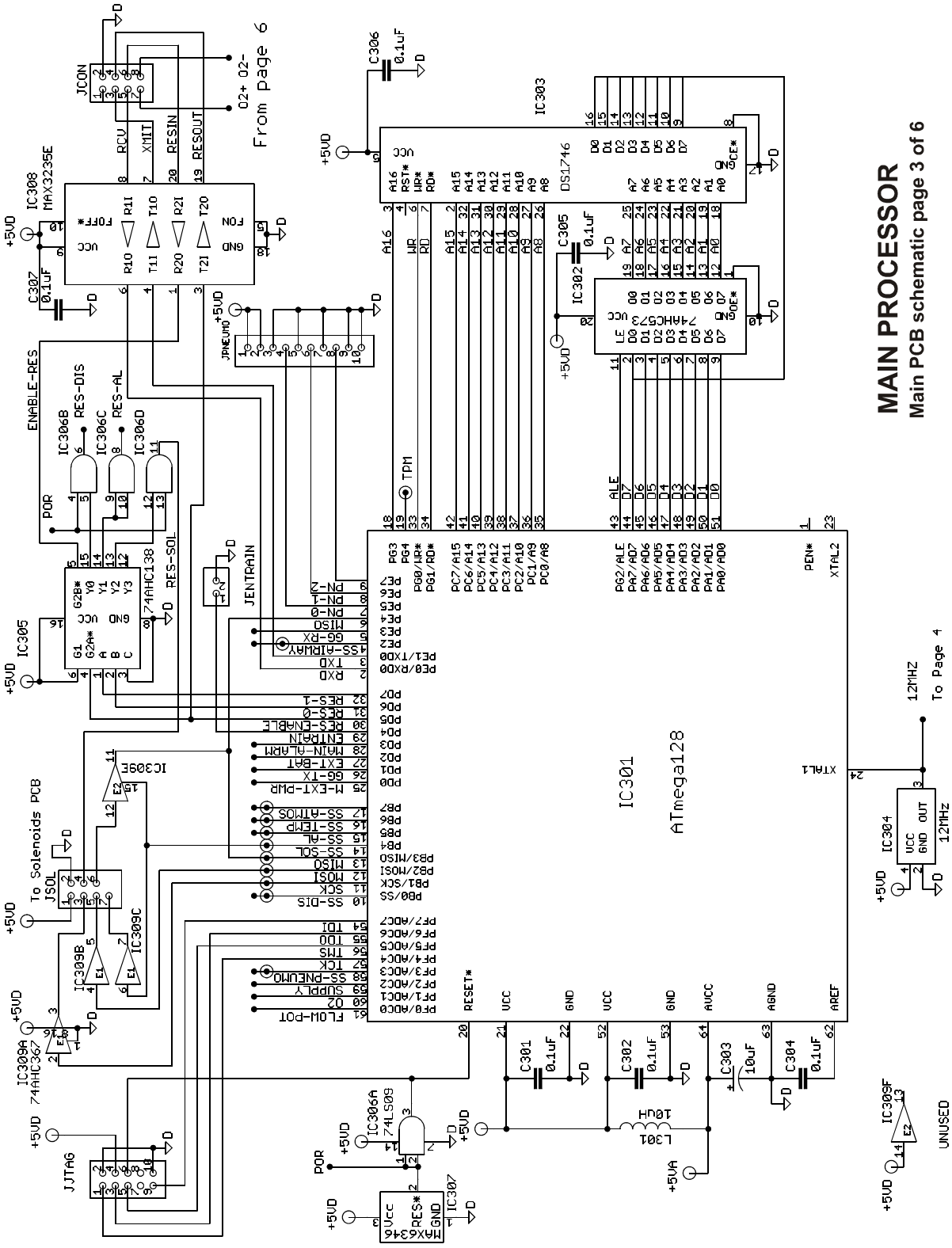
2- PCB BLOCK DIAGRAM

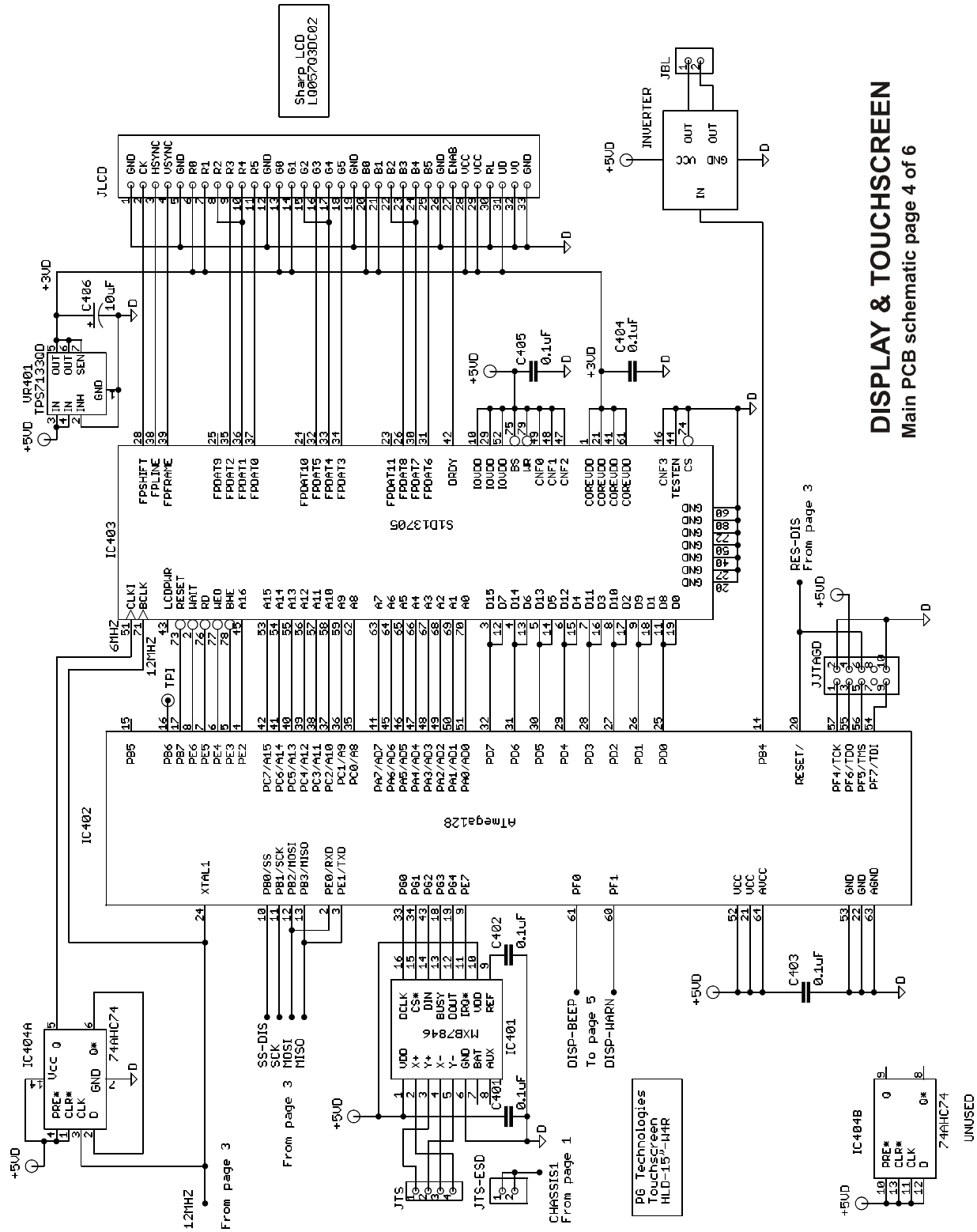


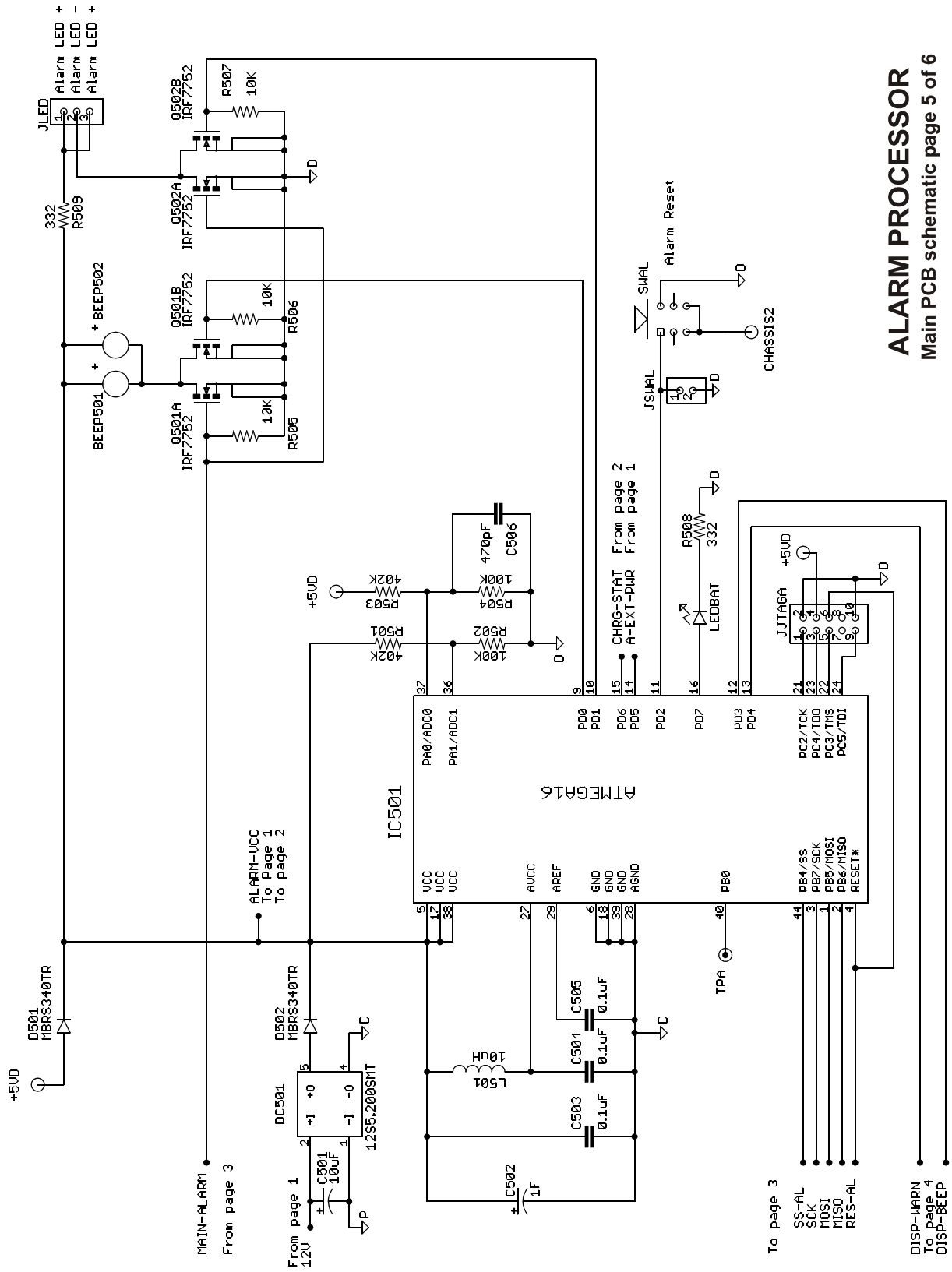
3- CIRCUIT SCHEMATICS

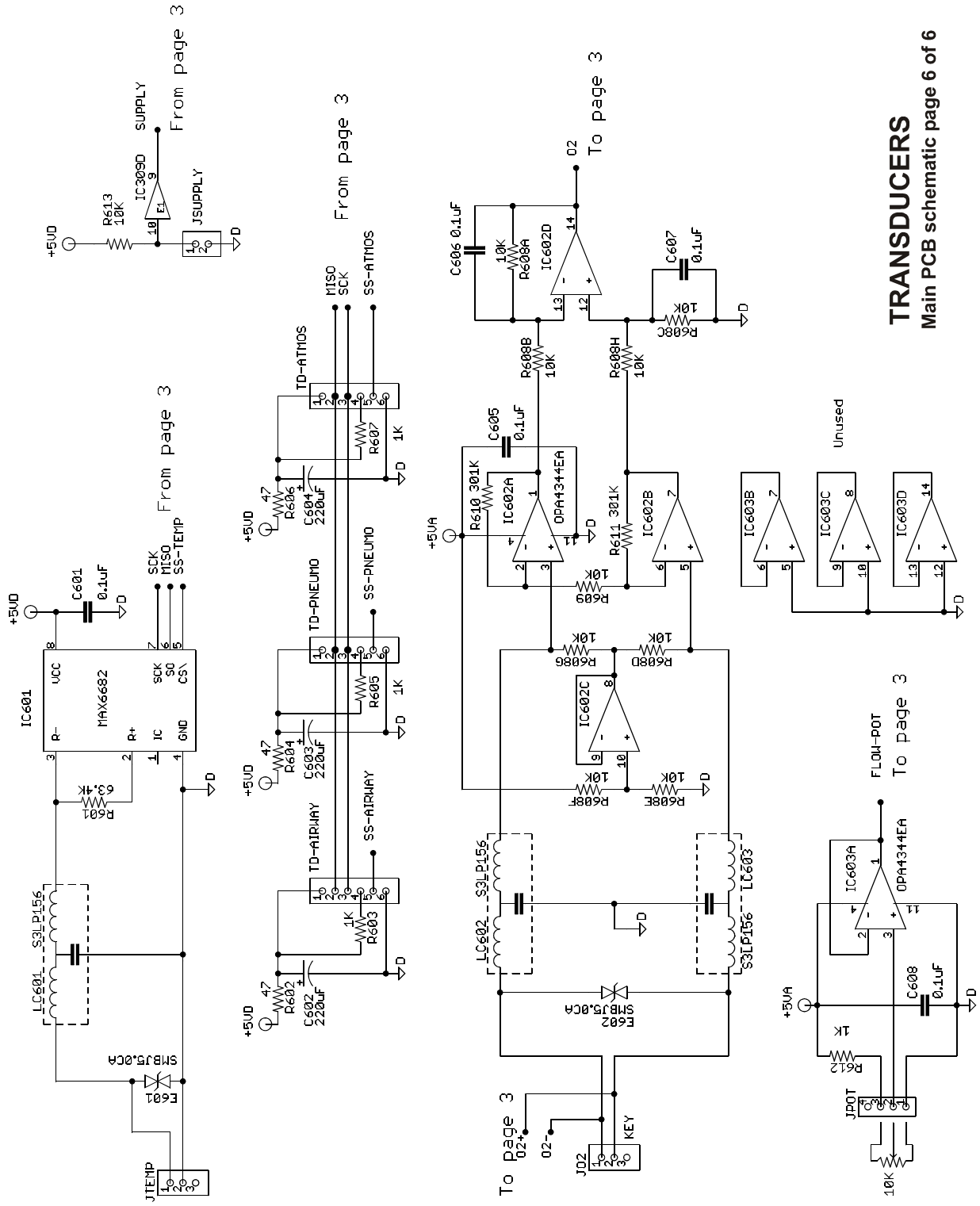


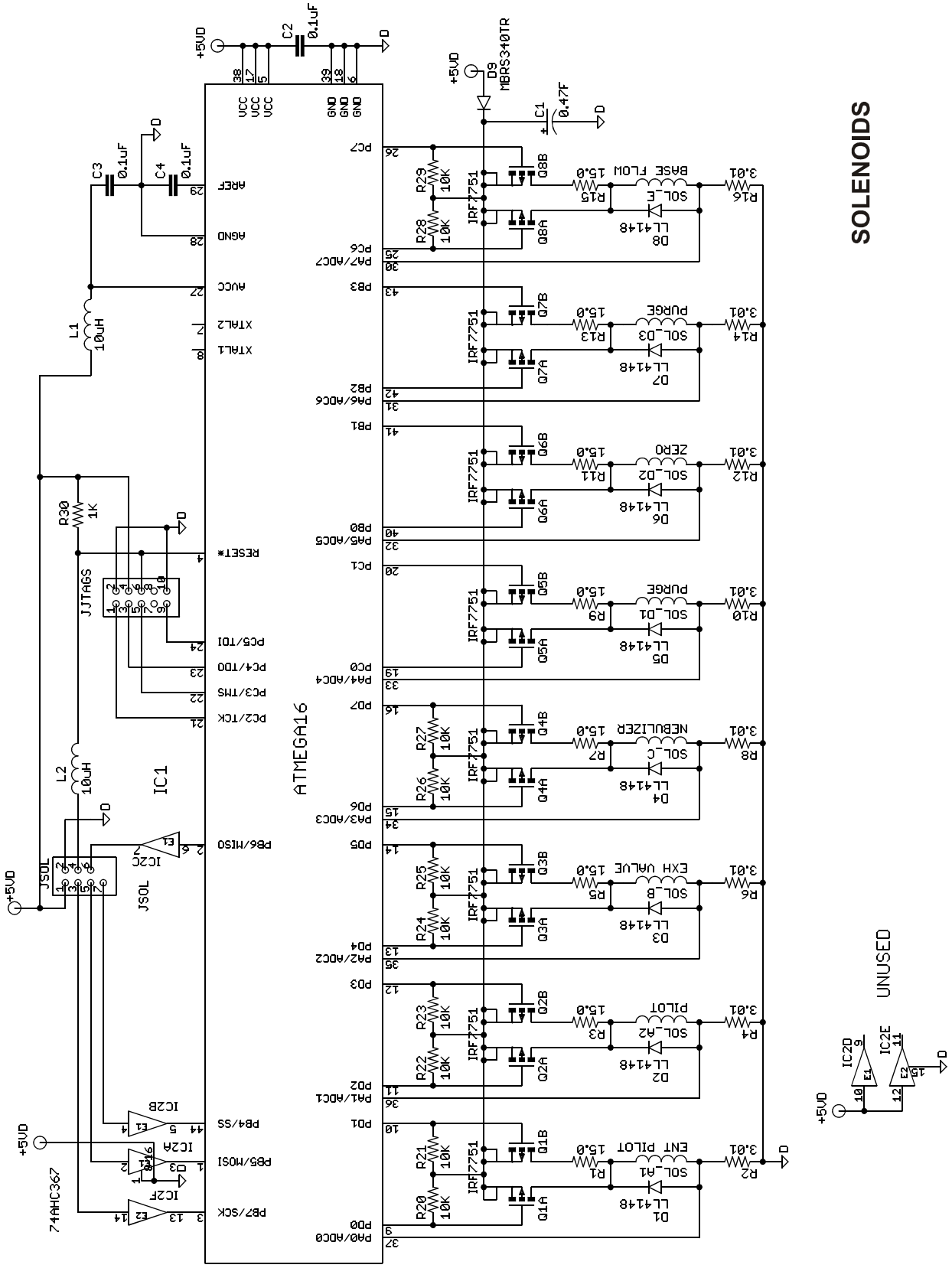

BATTERY CHARGER
Main PCB schematic page 2 of 6
BATTERY+
From page 1
JBATTERY
JBP
IC202
BQ2014H
LCOM
PR1
PR2
PR3
PR4
PR5
DONE
VSS
VCC
REF
NC
HDQ
RBI
SB
DISP
SR
R206 200K
R207 100K
C205 0.1uF
C204 1uF
C207 1uF
C206 0.1uF
C214 10uF
Q204 BSS138
D204 BAV99
R204 301K
R205 806K
C203 0.1uF
R218 100K
R216 750K
R217 150K
R215 1.62K
C213 1000pF
100K R214
C212 0.1uF
L201 220uH
D203 MBRS340TR
R213 0.02 3W
Q202 FCX1149A-T
IC201
BQ2000T
SNS
VSS
LED
BAT
MOD
VCC
RC
TS
C211 4.7pF
C210 0.1uF
R202 7.5
R203 7.5
MMBT2222A Q203
1K 1/4W R201
R208 9.31K
R210 100K
R209 14.3K
MMBT2222A Q201
D202 LL4148
C202 1000pF
C209 0.1uF
JCD
C cells
D cells
R212 47K
R211 75K
C201 220uF
R219 470
OC201 TLP112A
C208 0.1uF
C215 0.1uF
D201 MBRS340TR
From page 1 12V
From page 1
UR201 uA78L05CD
IN
OUT
GND
ALARM-VCC
To page 5 CHRG-STAT
GG-TX
To page 3
GG-RX
+5VD
Q205 2N3906
R223 2K
R222 470
OC203 TLP112A
R221 2K
OC202 TLP112A
R220 470

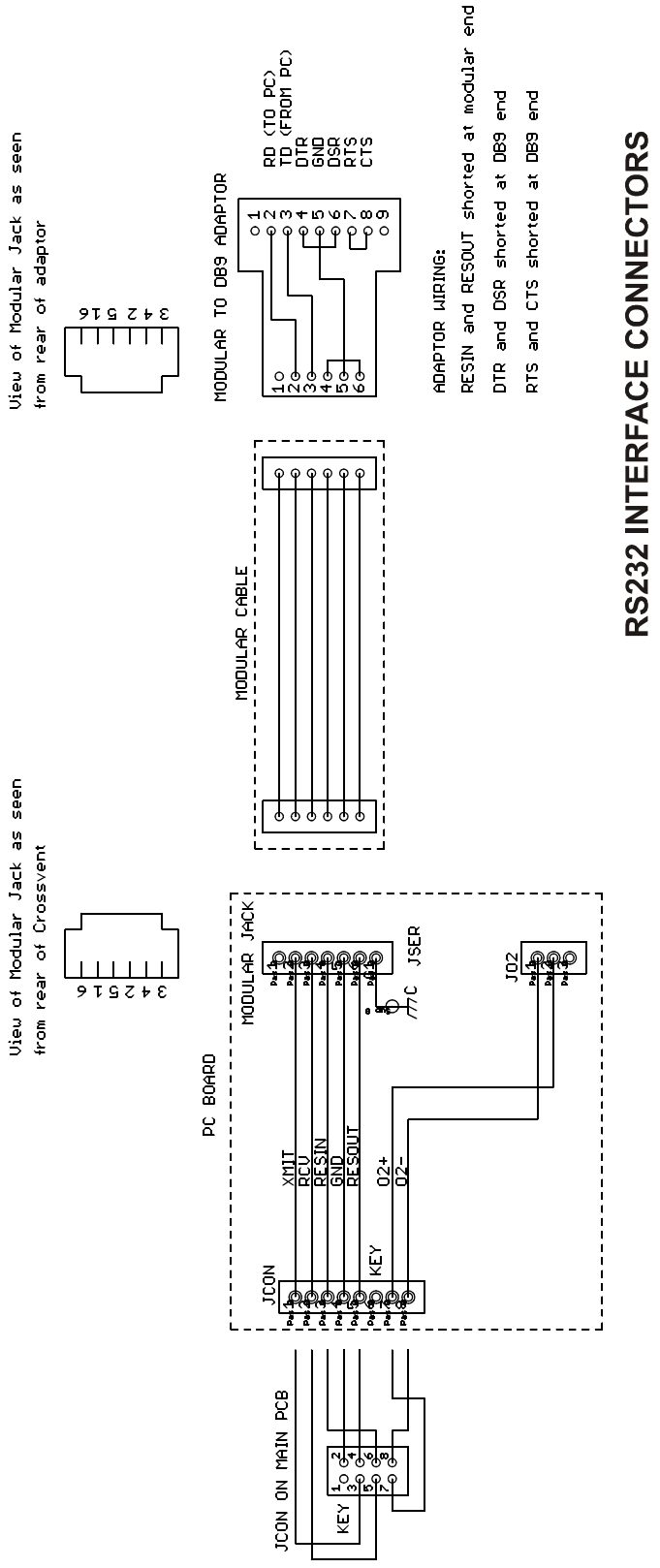

MAIN PROCESSOR
Main PCB schematic page 3 of 6
IC301
ATmega128
IC303
DS1746
IC302
74AHC573
IC308
MAX3235E
IC305
74AHC138
IC309A
74AHC367
IC306A
74LS09
IC307
X4643
IC304
12MHZ
C301
C302
C303
C304
C305
C306
0.1uF
10uF
10uH
L301
JCON
JSOL
JJTAG
JENGINE
JENTRAIN
ENABLE-RES
RES-DIS
RES-AL
RES-SOL
POR
+5VD
+5VA
From page 6
To Page 4
To Solenoids PCB
UNUSED


DISPLAY & TOUCHSCREEN
Main PCB schematic page 4 of 6
Sharp LCD
LQ057Q3DC02
JLCD
INVERTER
JBL
IC403
SED1375
IC402
Atmega128
IC401
MX7846
IC404A
IC404B
74AHC74
UR401
TPS71330D
C406
10uF
C405
C404
C402
C403
0.1uF
JTAGD
JTS
JTS-ESD
RES-DIS
From Page 3
SS-DIS
SCK
MOSI
MISO
From page 3
12MHZ
6MHZ
DISP-BEEP
DISP-WARN
To page 5
CHASSIS1
From page 1
PG Technologies
Touchscreen
HLD-15"-W4R
UNUSED

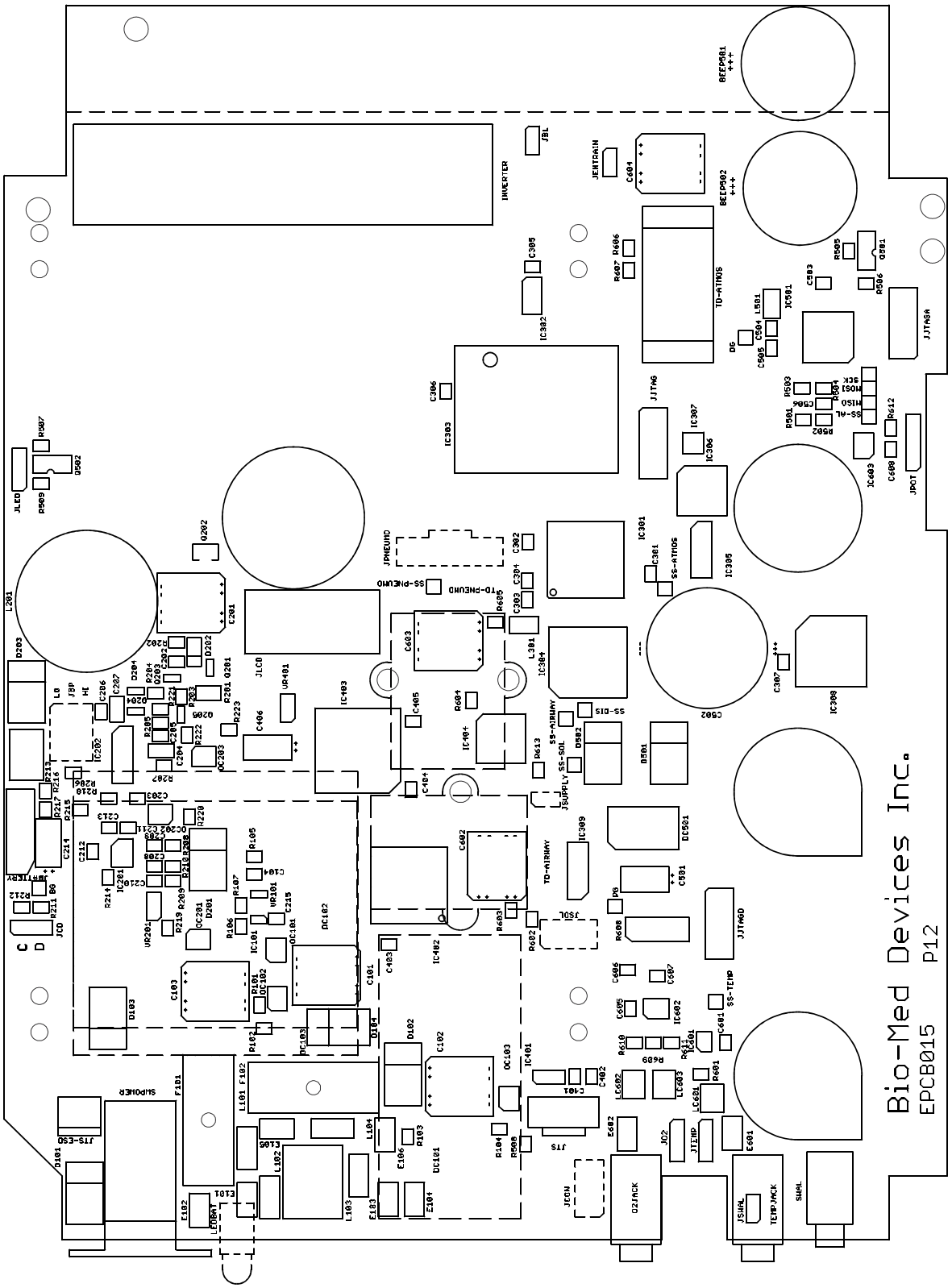

ALARM PROCESSOR
Main PCB schematic page 5 of 6
JLED
Alarm LED +
Alarm LED -
Alarm LED +
Q502B IRF7752
Q502A IRF7752
Q501B IRF7752
Q501A IRF7752
R507 10K
R506 10K
R505 10K
R509 332
BEEP502
BEEP501
SWAL
Alarm Reset
CHASSIS2
JSWAL
R508 332
LEDBAT
JJTAGA
+5VD
CHRG-STAT From page 2
A-EXT-PWR From page 1
R503 402K
R501 402K
R504 100K
R502 100K
C506 470pF
IC501
ATMEGA16
PA0/ADC0
PA1/ADC1
PD0
PD1
PD6
PD5
PD2
PD7
PD3
PD4
PC2/TCK
PC4/TDO
PC3/TMS
PC5/TDI
VCC
VCC
VCC
AVCC
AREF
GND
GND
GND
AGND
PB0
PB4/SS
PB7/SCK
PB5/MOSI
PB6/MISO
RESET*
ALARM-VCC
To Page 1
To page 2
D501 MBRS340TR
D502 MBRS340TR
DC501
+I +O
-I -O
12S5.200SMT
C501 10uF
C502 1F
C503 0.1uF
C504 0.1uF
C505 0.1uF
L501 10uH
TPA
MAIN-ALARM
From page 3
From page 1
12V
To page 3
SS-AL
SCK
MOSI
MISO
RES-AL
DISP-WARN
To page 4
DISP-BEEP


TRANSDUCERS
Main PCB schematic page 6 of 6
From page 3
To page 3
+5VD
+5VA
SCK
MISO
SS-TEMP
SS-ATMOS
SS-PNEUMO
SS-AIRWAY
TD-ATMOS
TD-PNEUMO
TD-AIRWAY
IC601
MAX6682
C601 0.1uF
R601 63.4K
LC601 S3LP156
LC602 S3LP156
LC603 S3LP156
E601 SMBJ5.0CA
E602 SMBJ5.0CA
JTEMP
JSUPPLY
JD2
JPOT
KEY
SUPPLY
IC309D
R613 10K
R602 47
R603 1K
R604 47
R605 1K
R606 47
R607 1K
C602 220uF
C603 220uF
C604 220uF
C605 0.1uF
C606 0.1uF
C607 0.1uF
C608 0.1uF
IC602A
IC602B
IC602C
IC602D
OPA4344EA
R610 301K
R611 301K
R608A 10K
R608B 10K
R608C 10K
R608D 10K
R608E 10K
R608F 10K
R608G 10K
R609 10K
O2+
O2-
O2
IC603A
IC603B
IC603C
IC603D
Unused
FLOW-POT
R612 1K
10K

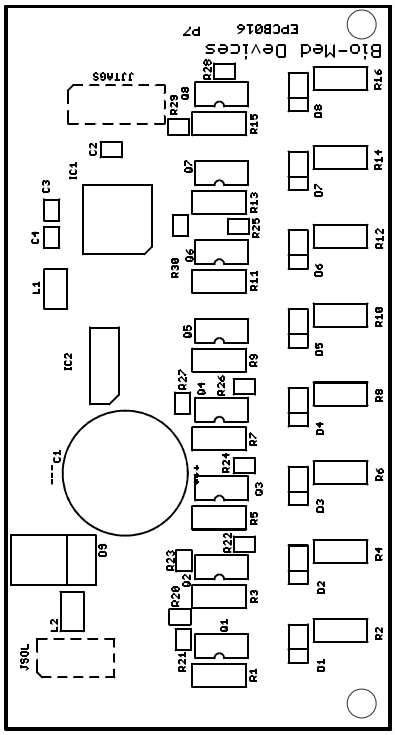

SOLENOIDS
ATMEGA16
IC1
74AHC367
UNUSED
+5VD
C1
0.47F
C2
0.1uF
C3
0.1uF
C4
0.1uF
L1
10uH
L2
10uH
R30
1K
D9
MBRS340TR
JTAGS
JSOL
BASE FLOW
PURGE
ZERO
NEBULIZER
EXH VALVE
PILOT
ENT PILOT
SOL_E
SOL_D3
SOL_D2
SOL_D1
SOL_C
SOL_B
SOL_A2
SOL_A1
D8
D7
D6
D5
D4
D3
D2
D1
Q8B
Q8A
Q7B
Q7A
Q6B
Q6A
Q5B
Q5A
Q4B
Q4A
Q3B
Q3A
Q2B
Q2A
Q1B
Q1A
IRF7751
LL4148
R29
R28
R27
R26
R25
R24
R23
R22
R21
R20
10K
R16
R15
R14
R13
R12
R11
R10
R9
R8
R7
R6
R5
R4
R3
R2
R1
3.01
15.0
RESET*
AREF
AGND
AVCC
XTAL2
XTAL1
VCC
GND
PC7
PA7/ADC7
PB3
PA6/ADC6
PB1
PA5/ADC5
PC1
PA4/ADC4
PD7
PA3/ADC3
PD5
PA2/ADC2
PD3
PA1/ADC1
PD1
PA0/ADC0
PC5/TDI
PC4/TDO
PC3/TMS
PC2/TCK
PB6/MISO
PB4/SS
PB5/MOSI
PB7/SCK
PD0
IC2C
IC2B
IC2A
IC2F
IC2D
IC2E


RS232 INTERFACE CONNECTORS
ADAPTOR WIRING:
RESIN and RESOUT shorted at modular end
DTR and DSR shorted at DB9 end
RTS and CTS shorted at DB9 end
MODULAR TO DB9 ADAPTOR
RD (TO PC)
TD (FROM PC)
DTR
GND
DSR
RTS
CTS
View of Modular Jack as seen from rear of adaptor
3 4 2 5 1 6
MODULAR CABLE
View of Modular Jack as seen from rear of Crossvent
3 4 2 5 1 6
PC BOARD
MODULAR JACK
J3
J2
XMIT
RCV
RESIN
GND
RESOUT
O2+
O2-
KEY
JCON
JCON ON MAIN PCB
KEY

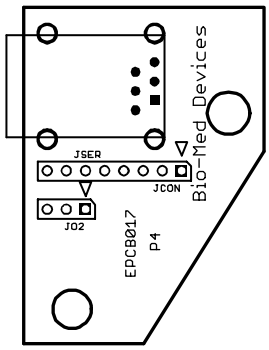
MAIN COMPONENT LOCATIONS



SOLENOID COMPONENT LOCATIONS



RS232 CONNECTOR PCB



WARRANTY

BIO-MED DEVICES, INC. expressly warrants to the PURCHASER, this Ventilator to be free from defects in material and workmanship for a period, from the date of purchase of one (1) year. BIO-MED DEVICES, INC. will repair or, at its option, replace any part or all of this ventilator which fails to conform to this warranty at no cost to the PURCHASER for materials and labor. The warranty does not apply to the patient circuit and hoses supplied with the instrument nor does the warranty cover abuse or misuse of the instrument, or damage due to unauthorized servicing.

BIO-MED DEVICES, INC. will pay any shipping charges required in repairing or replacing any part or all of this ventilator within three (3) months from the date of purchase. Thereafter, shipping charges will be paid by the PURCHASER.

THIS WARRANTY IS EXPRESSLY MADE IN LIEU OF THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE AND ALL OTHER WARRANTIES EXPRESS OR IMPLIED.

This warranty shall become null and void if the Ventilator is opened, otherwise tampered with or if repairs are attempted by the PURCHASER, or if the Ventilator is operated by anyone other than trained and duly qualified medical personnel, or if the "Warranty Registration Card" is not returned within four (4) weeks of the date of purchase to:

BIO-MED DEVICES, INC.
61 Soundview Road
Guilford, CT 06437 USA
203-458-0202

APPENDIX A

ABBREVIATIONS

BPM	-	Breaths Per Minute
BPH	-	Breaths Per Hour
LPM	-	Liters Per Minute
ms	-	Milliseconds
ml	-	Milliliters
C	-	Degrees Centigrade
F	-	Degrees Fahrenheit
cmH_2O	-	Centimeters of Water Pressure
ml/ cmH_2O	-	Milliliters Per Centimeter Water
L	-	Liters
VAC	-	Volts of Alternating Current
VDC	-	Volts of Direct Current
HZ	-	Hertz (Cycles Per Second)
LED	-	Light Emitting Diode
LCD	-	Liquid Crystal Display
psi	-	Pounds Per Square Inch
kPa	-	kilopascals
Kg/cm^2	-	Kilograms Per Centimeter Square
PEEP	-	Positive End Expiratory Pressure
CPAP	-	Continuous Positive Airway Pressure
SIMV	-	Synchronized Intermittent Mandatory Ventilation
DISS	-	Diameter Index Safety System
I	-	Inspiratory Time
E	-	Expiratory Time
I/E	-	Inspiratory To Expiratory Ratio
TV	-	Tidal Volume
INSP	-	Inspiratory
EXP	-	Expiratory
EXH	-	Exhalation
PROX.	-	Proximal
TEMP	-	Temperature
dB	-	Decibels
D.A.R.V.	-	Diaphragm Actuated Relief Valve
WEEE	-	Waste from Electrical and Electronic Equipment
PCB	-	Printed Circuit Board
A/C	-	Assist Control
PEF	-	Peak Expiratory Flow
BATT		Battery

APPENDIX B

DEFAULT SETTINGS

These are the settings that will be made by the software if all power to memory is lost .

Mode: Assist Control
Rate: 12 bpm
Tidal Volume: 500ml
Pressure Trigger: 1 cmH_2O
SIMV rate: 4 bpm
Sigh: off
Pressure support: off

Alarm limits:	Peak low	63
	Peak high	64
	Rate low	78
	Rate high	79
	ExhMV low	49
	ExhMV high	50
	ExhTV low	1599
	ExhTV high	1600
	PEEP low	49
	PEEP high	50
	Mean low	62
	Mean high	63
	O2 low	61
	O2 high	62

Language: English

APPENDIX C

SUMMARY OF PARAMETER RANGES / ACCURACIES

PARAMETER	RANGE	RESOLUTION OF DISPLAY	ACCURACY
Rate	5- 150bpm	.1 bpm below 10; 1 bpm above 10	±10%
Tidal Volume	5- 2500ml	1ml below 200; 10 ml above 200	±10%[1]
Flow Rate	1- 120 lpm	.1 lpm below 10; 1 lpm above 10	±10% [2]
Peak Pres	0- 120 cmH_2O	1 cmH_2O	±3% FS
PEEP Pres	0- 35 cmH_2O	1 cmH_2O (above baseline)	±3cm H_2O
Pressure Trigger	-10 to -0.2cm	.1 cmH_2O below 3; 1cm above 3	±1cm H_2O
Press Supp.	0- 50 cmH_2O	1 cmH_2O (above baseline)	±3cm H_2O
SIMV Rate	.6- 50bpm	Same as Rate	±10%
O_2 sensor	18- 100%	1%	±3% FS
EXHTV	50– 3200 ml	1 ml below 200; 10 ml above 200	±15%[3]
EXHMV	0-45 L	0.1 L below 10 L, 1 L above 10 L	±15%

[1] Accurate from 100-2500 ml

[2] Accurate from 1-120 lpm ±10% of setting or 1 lpm, whichever is greater. With entrainment on, flow accuracy from 5 - 100 LPM is ±10% or 1 LPM, whichever is greater, and with a flow of 100 LPM and over, flow accuracy is within 15% of displayed flow. No accuracy is claimed below 5 LPM.

[3] Readings below 100 ml may be considered relative rather than absolute values.

APPENDIX D

SUMMARY OF DISABLED FUNCTIONS

DISABLING FUNCTION	PARAMETER DISABLED
CPAP.....	SIGH

APPENDIX E

AUDIBLE ALARM CODES

CAUSE	AUDIBLE SEQUENCE	
COMMON ALARM DUE TO VIOLATION OF LIMITS	1 LONG	___
LOSS OF POWER (INCLUDES TURNING OFF)	1 LONG	___
INTERFACE PROCESSOR FAILURE	2 LONG	___ ___
SOLENIOD PROCESSOR FAILURE	3 LONG	___ ___ ___
SOLENOID A	1 LONG, 1 SHORT	___ •
SOLENOID B	1 LONG, 2 SHORT	___ • •
PROCESSOR COMMUNICATION OR TRANSDUCER ERROR	1 LONG, 3 SHORT	___ • • •
SOLENOID D1	2 LONG, 1 SHORT	___ ___ •
SOLENOID D2	2 LONG, 2 SHORT	___ ___ • •
SOLENOID D3	2 LONG, 3 SHORT	___ ___ • • •
BEEPER CONTROL CIRCUIT	CONTINUOUS	CONTINUOUS

APPENDIX F

CHARGERS AND INVERTERS

This explains some of the requirements for connecting a Bio-Med Devices Crossvent ventilator to a charger or AC adapter. It is important that the correct charger be used and if a Crossvent is to be used in a vehicle with an AC generating device (inverter), it must comply with certain requirements.

1. LAND OPERATION

When using an AC adaptor to either run the Crossvent or to charge the batteries, only the Jerome Industries model WSZ116M (16VDC 3A) charger supplied by Bio-Med Devices should be used.

The Bio-Med charger has been thoroughly tested for proper operation with the Crossvent to make sure that all standards are met. This includes all of the applicable standards for safety, EMI/RFI, power surges, and leakage. It is approved for medical applications and conforms to FDA, CE, UL, and other required standards.

Although other forms and brands of chargers may operate the Crossvent, there is no guarantee of system reliability or conformance to required standards.

Should an emergency arise and it becomes necessary to operate the Crossvent without the Bio-Med charger, use only a charger that is approved for medical use and complies with all applicable standards. It must produce filtered DC voltage ranging between 12 and 28 volts DC and be rated for continuous 2.5 amps of current.

Should a Crossvent fail to operate or charge from a charger, both the Crossvent and the charger should be returned together to Bio-Med Devices for evaluation.

2. AIR OPERATION – FIXED OR ROTARY WING AIRCRAFT

The aircraft industry is constantly making technical advancements in the areas of composite material construction and weight reduction of installed equipment. Unfortunately, this can conflict with the safe operation of some electronic medical equipment. Composite materials do not work well as a grounding agent for electronic equipment. The weight reduction techniques used in AC inverters often create unsafe conditions when operating electronic medical equipment.

The Crossvent is designed to operate from an external power source delivering 12 to 28 volts DC at a continuous current of 2.5 amps.

It is best to operate the Crossvent from the aircraft's 24-volt DC battery source, rather than an AC inverter. To insure the best "grounding" between the Crossvent and the aircraft metal frame, connect the Crossvent directly to the 24-volt DC power bus through appropriate fusing. This will keep extraneous interference and current leakage to a minimum.

3. INVERTER OPERATION

If it is necessary to operate the Crossvent from an AC inverter, similar to KGS Electronics brands, only those inverters in compliance with NEMA standards should be used. Inverters with "split winding" output transformers should not be used with the Crossvent and supplied charger.

The inverter output must be configured like standard household or industrial wiring, where the black wire is "hot", the white wire is "neutral", and the green wire is "ground". The neutral and ground wires should be connected together at one point of the frame so that there is no voltage between them, and there should be 115 volts AC between the hot and neutral wires.

The inverter receptacles must be of the standard three-prong configuration to utilize the hospital-grade cord of the Bio-Med supplied charger. This will keep voltage surges, spurious noise and leakages to a minimum.

Any other type of AC/DC power supply or charger, such as open frame devices, medically approved or not, is not recommended by Bio-Med Devices.

APPENDIX G

EUROPEAN AGENT

Bio-Med Devices' Official Agent in Europe is:

HORST HÖRNLA

H + H Intermed
Schwedenstraße 32
87463 Dietmannsried-Reicholzried
United Germany

Telefon: 08374-240620
Fax: 08374-2406262

INDEX

Abbreviations, 83
AC Power, 9, 10, 13
Accessories, 8
Accuracies, 85
Addendums, 12
Air Entrainment, 12
Airway Pressure, 14
Alarm Beeper, *11*
Alarm Menus, 19
Alarm Quiet, 5, 21
Alarm Reset Switch, 14
Alarms, 12, 19
Assist Control, 17, 36
Assisted Breath, 22
Backlight, 16
Backup Rate, 18, 39
Battery, 1, 5, 9, 13, 22
Battery Charging, 13
Battery Replacement, 58
Beeper. *See* Alarm Beeper
Blender, 11
Breathing Circuit. *See* Patient Circuit
Calibration Menu (CAL), 40
Calibration, Pneumatic, 51
Cautions, 1, 4
CE Mark, 15
Charger. *See* Power Supply
Charging LED, 13
Cleaning, 31
CMV, 17, 36
Connections, 23
Connectors, 13, 14
Contrast. *See* Intensity
Controlled Breath, 22
CPAP, 11, 17, 38
D.A.R.V., 35
Deactivating Alarms, 21
Default Settings, 84
Dimensions, 10
Disabled Functions, 86
Disassembly, 58
Display Test, 41
Entrainment, 12
Entrainment (ENTRN), 22
European Agent, 89
Exhaled Tidal Volume, 19, 21
External Power, 5, 10, 22
Factory Service, 42
Fail to Cycle, 5
Filter, 35
Filter Replacement, 64
Flow, 11, 16, 18
Flow Calibration, 43, 56
Flow Sensor, 14
Flush, 34
Gas Supply, 4, 23
Hours, 42
I/E Ratio, 16
Inspiratory, 18, 22, 27
Inspiratory Effort, 17
Intensity, 16
Keys, 16, 41
Languages, 27
Leak Test, 27
LED, Alarm, 11, 14
LED, Charging, 13
Lock, 21
Main Menu, 17
Manual, 17, 22
Max Press. *See* Maximum Pressure
Maximum Pressure, 11
Mode Selection, 16
MRI, 9
Notes, 1, 5
Oxygen Sensor, 4, 14, 27
Oxygen Sensor Tee, 31
Parameter Ranges, 85
Parts List, 67
Patient Circuit, 24
Peak Pressure, 20
PEEP, 11, 17
Performance Checks, 43
Pneumotach. *See* Flow Sensor
Power, 10, 22
Power Supply, 10, 13
Pressure Calibration, 57
Pressure Support, 37
Pressure Transducer Calibration, 57
Preventative Maintenance, 48
Preventative Maintenance Parts, 48, 64
Quick Setup, 26
Rate, 18, 20
Reusable Circuit, 31
RS-232, 50
Schematics, Electronic, 72
Sensitivity, 17
Setup Menu, 27, 40
SIMV, 17, 18, 37
SIMV Rate, 18, 37
Software Upgrade, 50
Specifications, 10
Spontaneous (SPONT), 22
Spontaneous Breaths, 17
Sterilizing, 31
Symbols, 7
Tee, Oxygen Sensor. *See* Oxygen Sensor Tee
Temperature, 10
Test Equipment, 47

Tidal Volume, 18, 27
Tools, 47
Touchscreen Calibration, 41
Transducer, 35
Troubleshooting, Operational, 29
Troubleshooting, Technical, 65
TV. *See* Tidal Volume
Valves, 42
Warnings, 1
Warranty, 82
Weight, 10